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DEPARTMENT OF HEALTH AND HUMAN SERVICES

5 CFR Parts 5501 and 5502

RIN 3209-AA15

Supplemental Standards of Ethical Conduct and Financial Disclosure Requirements for Employees of the Department of Health and Human Services

AGENCY: Department of Health and Human Services (HHS).

ACTION: Interim final rule with request for comments.

SUMMARY: The Department of Health and Human Services, with the concurrence of the Office of Government Ethics (OGE), is amending the HHS regulation that supplements the OGE Standards of Ethical Conduct. This interim final rule specifies additional procedural and substantive requirements that are necessary to address ethical issues at the National Institutes of Health (NIH) and updates nomenclature, definitions, and procedures applicable to other components of the Department. The rule: Revises the definition of a significantly regulated organization for the Food and Drug Administration (FDA); Updates the organization titles of designated separate agencies; Amends the gift exception for native artwork and craft items received from Indian tribes or Alaska Native organizations; Aligns the FDA prohibited holdings limit with the de minimis holdings exemption in OGE regulations; Revises prior approval procedures for outside activities; and, subject to certain exceptions: Prohibits NIH employees from engaging in certain

outside activities with supported research institutions, health care providers or insurers, health-related trade or professional associations, and biotechnology, pharmaceutical, medical device, and other companies substantially affected by the programs, policies, or operations of the NIH; Bars NIH employees who file a public or confidential financial disclosure report from holding financial interests in substantially affected organizations; Subjects NIH non-filer employees to a monetary cap on holdings in such organizations; Specifies for NIH employees prior approval procedures for and limitations on the receipt of certain awards from outside sources; and Imposes a one-year disqualification period during which NIH employees are precluded from official actions involving an award donor. In addition, the Department is adding a new supplemental part to expand financial disclosure reporting requirements for certain outside activities and to ensure that prohibited financial interests are identified.

DATES: This interim rule is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Comments received by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER] will be considered prior to issuance of a final rule.

ADDRESSES: Send comments in writing to the Office of the General Counsel, Ethics Division, Department of Health and Human Services, Room 700-E, Hubert H. Humphrey Building, 200 Independence Avenue, SW, Washington, DC 20201, Attention: Linda L. Conte. Comments also may be sent electronically to the following e-mail address:

ethics@hhs.gov. For e-mail messages, the subject line should include the following reference: "Comments on Interim Final HHS Supplemental Ethics Rule."

FOR FURTHER INFORMATION CONTACT: Edgar M. Swindell, Associate General Counsel, Office of the General Counsel, Ethics Division, Department of Health and Human Services, telephone (202) 690-7258, fax (202) 205-9752.

SUPPLEMENTARY INFORMATION:

I. Background

The Standards of Ethical Conduct for Employees of the Executive Branch, 5 CFR part 2635, establish uniform rules of ethical conduct applicable to all executive branch personnel. Pursuant to 5 CFR 2635.105, an agency may, with the approval of the Office of Government Ethics, supplement those standards with additional rules that the agency determines are necessary and appropriate, in view of its programs and operations, to fulfill the purposes of part 2635. On July 30, 1996, with the concurrence and co-signature of the OGE Director, HHS published at 61 FR 39755 a final rule establishing supplemental standards of ethical conduct for its employees. This interim final rule amends that final rule codified at 5 CFR part 5501.

In addition to several changes with respect to rules applicable to employees of the National Institutes of Health related to outside activities, financial holdings, and awards, this interim final rule makes several changes to the HHS Supplemental Standards of Ethical Conduct applicable to all Department employees. These changes are based on the

experience that has been garnered by the Department in implementing the regulation since it was issued in 1996. The interim final rule establishes more specific requirements with respect to requests for approval of outside activities and imposes an annual reauthorization process.

Although immediately effective, this is as an interim rule. HHS intends to evaluate certain provisions in the rule, particularly on outside activities and financial holdings, within the next year. During this time, HHS also will: (1) complete a review of existing outside activities that is presently ongoing; (2) evaluate possible effects on hiring and retention that may result from the imposition of outside activity and financial holdings prohibitions; and (3) develop a comprehensive oversight system to address concerns raised about the NIH ethics program.

In addition, the Executive Branch Financial Disclosure Regulation, 5 CFR part 2634, specifies uniform rules governing the public and confidential financial disclosure systems established under the Ethics in Government Act. Pursuant to 5 CFR 2634.103, an agency may, subject to the prior written approval of the Office of Government Ethics, issue supplemental financial disclosure regulations that are necessary to address special or unique circumstances. This interim final rule amends chapter XLV of title 5 by adding new part 5502 to provide for an annual reporting by all employees of financial and other information concerning outside activities and a supplemental disclosure by all FDA and NIH employees with respect to prohibited financial interests.

Post-promulgation comments on this interim final rule are requested. Those comments and experience under the interim rule will inform the development of a final permanent rule, in consultation with OGE.

II. Analysis of the Amendments

A. Supplemental Standards of Ethical Conduct

Section 5501.101 General

The definition of a "significantly regulated organization" found at § 5501.101(c)(2) is amended to make clear that for entities that do not have a record of sales of FDA-regulated products, and which have not yet commenced operations in a field regulated by FDA, an entity will nonetheless be deemed significantly regulated if its research, development, or other business activities are reasonably expected to result in the development of products that are regulated by FDA.

Since the issuance of the HHS Supplement, the existing language of the regulation has suggested to some employees that until a company submits an investigational new drug application and begins conducting clinical trials, the company is not significantly regulated (assuming there is no record of prior sales of FDA-regulated products). Because FDA does not have a generalized authority to regulate the "field" of scientific research, some employees have interpreted the existing regulation as permitting employment with a company that is thus far only conducting preliminary research, even when it is reasonable to conclude that the research is conducted with the aim of developing FDA-regulated products.

Accordingly, this amendment ensures that newly-formed business entities that do not yet have products that are approved for sale, and which have not yet undertaken operations that bring them within FDA's regulatory jurisdiction, will be understood to fall

within the definition of significantly regulated if their research, development, or other business activities are reasonably expected to result in the development of products that are regulated by FDA. It also makes clear that where a company's operations are regulated by FDA, to fall within the definition, the operations need not be entirely in areas regulated by FDA as long as they are primarily in such areas.

Section 5501.102 Designation of HHS components as separate agencies

The changes to this section reflect the name change of two HHS agencies, the Agency for Healthcare Research and Quality, previously known as the Agency for Health Care Policy and Research, and the Centers for Medicare and Medicaid Services, previously known as the Health Care Financing Administration. The Office of Consumer Affairs was abolished in 1998 and is deleted from the list. In addition, the amendment specifies that the designation of separate agencies will apply in defining a prohibited source for purposes of the new awards rule in § 5501.111 for NIH employees.

Section 5501.103 Gifts from federally recognized Indian tribes or Alaska Native villages or regional or village corporations

The change to this section clarifies that items representative of traditional native culture from federally recognized Indian tribes or Alaska Native villages, or regional or village corporations, fall within the previously established rule permitting HHS employees to accept gifts of native artwork and crafts, provided that the aggregate market value of individual gifts received from any one tribe or village does not exceed $200 per

year and other criteria are satisfied. The amendment permits gifts that, while representative of traditional native culture, were not necessarily produced or manufactured by the donor entity.

Section 5501.104 Prohibited financial interests applicable to employees of the Food and Drug Administration

The section heading and text have been revised to delete redundant references to the "FDA Office of the Chief Counsel." Section 5501.102(b)(1) already specifies that any section in part 5501 that is made applicable to employees of an identified component that is designated as a separate agency is applicable, in addition to employees actually working within a component, to employees in a division or region of the Office of the General Counsel (OGC) that principally advises or represents that component.

Section 5501.104(a) prohibits FDA employees from holding financial interests in significantly regulated organizations, subject to certain exceptions in § 5501.104(b). The change in paragraph (b)(1) broadens the scope of the exception, which previously covered only pension interests, such as those arising from participation in defined benefit or defined contribution plans. Experience since the issuance of the supplemental regulation indicates that many incoming employees hold financial interests which, like a pension interest, were acquired as a form of compensation from a significantly regulated organization, but which do not qualify as a pension. For example, a recent report by the National Academy of Sciences found that stock and stock options are common employee benefits in small, private technology firms in the fields of engineering and health care,

and the report recommended against forced divestiture of such employee benefits for scientists entering public service, as such requirements may unreasonably hamper the recruitment of talented and experienced scientific personnel. National Academy of Sciences, Science and Technology in the National Interest: Ensuring the Best Presidential and Federal Advisory Committee Science and Technology Appointments 199-201 (2004). Therefore, the exception has been amended to include not only pensions but other employee benefits.

This exception is not intended to permit retention of financial interests merely because the interest was purchased by an employee contemporaneously with employment in private industry through a broker, financial advisor, or other source not acting as part of the private employer's compensation system.

In addition, like all the exceptions in this section, the provision merely permits retention of a financial interest notwithstanding the prohibited financial holdings provision of this section. The recusal requirements of 18 U.S.C. 208 apply to all financial interests, including those covered by the exceptions in this section. (References to § 208 within this regulation are descriptive and not intended to interpret or expand upon the text of the statute.) Moreover, all financial interests are subject to directed divestiture pursuant to 5 CFR 2635.403(b), when there has been a determination by the agency that holding the particular financial interest, or a class of financial interests, will require the employee's disqualification from matters so central or critical to the performance of his official duties that the employee's ability to perform the duties of his office would be materially impaired, or will adversely affect the efficient accomplishment of the agency's mission because another employee cannot readily be assigned to perform the work from which the employee is recused by reason of the financial interest.

Section 5501.104(b)(2) contains an exception to the prohibited holdings rule for employees who are not required to file a public or confidential financial disclosure report. Non-filers have been permitted to have a financial interest not exceeding $5,000 in significantly regulated organizations. The amendment raises the amount of the allowable holding to $15,000. The change parallels the increase from $5,000 to $15,000 in the OGE regulatory exemption for matters involving parties, found at 5 CFR 2640.202(a), that occurred after the original issuance of the HHS supplemental provision. The OGE exemption allows an employee to participate in any particular matter involving specific parties in which the disqualifying financial interest does not exceed $15,000 in publicly traded securities or long-term Federal Government or municipal securities. Because the allowable holding amount in the HHS Supplement corresponded to the OGE de minimis amount, an increase in the latter justifies an increase in the allowable holding limit in the HHS Supplement. Further, the section will track any future change in the OGE de minimis amount.

Although the dollar amounts are identical, the two provisions substantively are not coextensive. Not all financial interests that may be covered by the FDA exception will be covered by the OGE regulatory exemption. For example, the FDA exception permits a non-filer to hold a financial interest in a non-publicly traded company (assuming all the other criteria in the section are also satisfied), but the OGE regulatory exemption only applies when the corporate securities are publicly traded. Therefore, the financial interest may still be problematic under 18 U.S.C. 208 and require a recusal, a divestiture, or an individual waiver, even though § 5501.104(b)(2) excepts the holding from the FDA automatic divestiture requirement.

In applying the allowable holding amount, the existing section specifies that the asset value is to be measured "at the time of acquisition." The amendment to this section now defines that phrase. This change is intended to obviate the possibility of unintended situations which, depending on the interpretation of that phrase, could lead to treatment for some employees that is inconsistent with treatment of similarly-situated employees, and lead to results that are inconsistent with the intent of the provision. Specifically, there could be scenarios in which an employee who recently joined the agency, and who had acquired an asset in the distant past, could be permitted to retain an asset, now valued well over $15,000, because it had been valued under $15,000 "at the time of acquisition," while other new employees who acquired an asset more recently, but at a level above $15,000, are required to divest a much lower valued financial interest in the same or other significantly regulated organizations. Such inconsistent results in the implementation of the regulation could undermine the very purpose of the provision (i.e., that only de minimis holdings should be permitted) and undermine employee confidence that the regulation is being applied fairly and uniformly. Accordingly, this change is intended to make clear that for assets that were acquired prior to joining FDA, the "time of acquisition" will be deemed to be the date of the employee's entrance on duty at the agency. The change will prevent unfair and unwarranted inconsistencies in how the prohibited holding regulation is applied and will prevent situations in which employees are treated disparately, as a consequence of investment decisions made prior to their entrance on duty.

New § 5501.104(c) provides that, for purposes of determining the divestiture period specified in 5 CFR 2635.403(d), an employee is not considered to have been

directed to divest a financial interest prohibited under paragraph (a) of this section until the due date for disclosure of such interests. For new entrant employees, this disclosure would be submitted on either a public or confidential financial disclosure report or the supplemental report required by new § 5502.106(c), depending upon their filing status. For incumbent employees, the due date of the report required by § 5502.106(c) would be determinative. This rule allows the agency to analyze an employee's holdings and make a determination as to whether a particular financial interest is covered by the prohibition before the requirement to divest becomes applicable. The text codifies existing agency practice and parallels a similar provision in the Department of Housing and Urban Development supplemental ethics regulations at 5 CFR 7501.104(c) which prescribes a divestiture period of 90 days from the date a prohibited financial interest is reported.

Section 5501.106 Outside employment and other outside activities

The paragraph heading and introductory text of paragraph (c)(3) have been revised to delete redundant references to the FDA "Office of the Chief Counsel." Section 5501.102(b)(1) already specifies that any section in part 5501 that is made applicable to employees of an identified component that is designated as a separate agency is applicable, in addition to employees actually working within a component, to employees in a division or region of the Office of the General Counsel that principally advises or represents that component.

The amended paragraph (c)(4) provides that the attorneys in the Office of the Counsel to the Inspector General are subject to the same outside activities restrictions as those in the Office of the General Counsel.

The amended paragraph (d)(2)(i) adds employees of the NIH to the prior approval requirement, currently applicable to employees of the FDA, for any outside employment, whether or not for compensation, or any self-employed business activity.

The amended paragraph (d)(3) requires an employee's supervisor to review the request for approval of an outside activity and provide a statement addressing the extent to which the employee's duties are related to the proposed outside activity. This information shall then be forwarded to an agency designee to make a final determination with respect to the request. The amendment also specifies that the following information be included with the request: the employee's step within a grade, appointment type, and financial disclosure filing status; a description of how the employee's official duties will affect the interests of the outside employer; whether stock or other remuneration in cash or in-kind will be received in connection with the activity; the amount of compensation to be received in connection with the activity; the amount and date of compensation received, or due for services performed, within the prior six years; a syllabus, outline, summary, synopsis, draft, or similar description of content and subject matter if the activity involves teaching, speaking, or writing; and other information as determined by the designated agency ethics official, or the HHS component with the concurrence of the designated agency ethics official, to be necessary or appropriate to evaluate whether the request is prohibited by statute or regulation. Should other types of information be routinely required of all employees, general notice of such requirements will be disseminated through instructions or manual issuances and revisions to the forms that are utilized for these purposes.

The amendment to paragraph (d)(4) clarifies that a request for approval of outside employment or other outside activity may not be granted unless there is an affirmative determination that the employment or other activity is not expected to involve conduct prohibited by statute or regulation.

Existing paragraph (d)(5) has been renumbered as paragraph (d)(6). New paragraph (d)(5) specifies that approval of an outside activity is effective for one year only. Employees must renew their request for approval annually if they desire to continue any long term outside activity. In addition, employees must submit a revised request for approval if they change positions within the agency or if a significant change occurs in the nature of the outside activity or in the scope of the employees' duties.

Paragraph (e) incorporates a waiver provision to be used where, under the particular circumstances, application of the prohibited outside activity rules for FDA, OGC, or NIH employees is not necessary to ensure confidence in the impartiality and objectivity with which agency programs are administered. The waiver must not be inconsistent with part 2635 of this title or otherwise prohibited by law. This standard parallels the waiver provision at 5 CFR 3101.108(g) in the Department of the Treasury supplemental ethics regulation that imposes outside activity prohibitions applicable to employees of the Office of the Comptroller of the Currency. This provision could be applied to provide some relief, for example, where the prohibition unduly causes personal or family hardship or, prohibits an employee from completing a professional obligation entered into prior to Government service, or restricts the Department from securing necessary and uniquely specialized services.

Section 5501.109 Prohibited outside activities applicable to employees of the National Institutes of Health

Prior to the publication of this interim final rule, the criteria for approving or disapproving requests for approval of outside activities of NIH employees were set forth in the OGE regulation at 5 CFR part 2635, subpart H, and the Supplemental Standards of Ethical Conduct for Employees of HHS at 5 CFR 5501.106. Both the OGE rules and the HHS provisions in § 5501.106 remain in effect for all NIH employees. This interim final rule imposes additional, more stringent requirements, similar to those in 5 CFR 5501.106(c)(3) for employees of the FDA.

Outside activities with entities substantially affected by NIH programs, policies, or operations must be further restricted in order to avoid the potential for real or apparent conflicts of interest that may threaten the integrity of the critically important research conducted and sponsored by the NIH. This assessment is informed by recommendations of the Advisory Committee to the NIH Director that were presented in the June 22, 2004, Report of the NIH Blue Ribbon Panel on Conflict of Interest Policies (Blue Ribbon Panel Report), available at http://www.nih.gov/about/ethics_COI_panelreport.htm, but is predicated upon a consideration of various outside activities of NIH employees that have been subject to inquiry and the desire to advance sound public policy. Many of the panel recommendations and related issues were highlighted and discussed at Congressional hearings on outside consulting arrangements by NIH employees. Panel recommendations to liberalize certain current restrictions were not adopted in this rule. Additional restrictions are necessary because NIH operations increasingly require significant

interaction with pharmaceutical, biotechnological, biostatistical, and medical device companies (referred to within the regulation as "substantially affected organizations") and utilization of their products; the size and scope of NIH funding of biomedical and behavioral research, research training, and related activities have grown substantially; and NIH research findings are broad in range and influence within the health care sector. Moreover, in light of recent Congressional oversight and media reports, HHS has determined that the existing rules governing outside activities have not prevented reasonable public questioning of the integrity of NIH employees and the impartiality and objectivity with which agency programs are administered.

Through its approximately 17,500 full-time equivalent employees, NIH conducts biomedical and behavioral research, research training and related activities in its intramural program, and its extramural program funds those activities at universities, medical centers, research institutes and other nonprofit and for-profit organizations through grants, cooperative agreements, and contracts. Both the intramural and extramural programs interact with academic research institutions and substantially affected organizations in many ways, both formal (e.g., funding agreements, research agreements, intellectual property licenses, and research and development contracts) and informal (e.g., exchange of research materials and other research collaborations, public and private scientific discussions, and joint sponsorship of projects). The official actions of many NIH employees can affect the financial interests of a broad range of businesses and organizations, including health care providers and health insurers, often in subtle ways. Informed by recent experience, it is appropriate to limit broadly employees'

outside activities with those entities to avoid any appearance that official actions may be potentially influenced by private financial interests or loyalty to an outside employer.

The current HHS supplemental regulation on outside employment and other outside activities, 5 CFR 5501.106, prohibits employees of the NIH and other employees of HHS from providing certain services, for compensation, in the preparation of grant applications, contract proposals or other documents to be submitted to HHS, and from compensated outside employment with respect to a particular activity funded by an HHS grant, contract, cooperative agreement, or other funding mechanism authorized by statute, or conducted under a cooperative research and development agreement (CRADA).

Under § 5501.109(c)(1) of this interim final rule, subject to certain exceptions, all NIH employees are also prohibited from engaging in employment (which includes serving as an officer, director, or other fiduciary board member, serving on a scientific advisory board or committee, and consulting or providing professional services) and compensated teaching, speaking, writing, or editing with a substantially affected organization; a hospital, clinic, health maintenance organization, or other health care provider (defined comprehensively to include the types of entities that are eligible to receive payments under the Medicare program for the provision of health care items or services); a health insurer; a health, science, or health research-related trade, professional, consumer, or advocacy association; or a supported research institution.

A "substantially affected organization" is defined in paragraph (b)(8) to include those entities, irrespective of corporate form, that are engaged in the research, development, or manufacture of biotechnological, biostatistical, pharmaceutical, or

medical devices, equipment, preparations, treatments, or products. The term includes those organizations a majority of whose members are engaged in such activities.

Section 5501.109(b)(8)(iii) also permits the designated agency ethics official or, in consultation with the designated agency ethics official, the NIH Director or the NIH Director's designee to determine that other entities shall be classified as substantially affected organizations. These determinations will be based upon whether such entities are engaged in activities that are substantially affected by the programs, policies, or operations of the NIH and whether, in view of the ongoing research conducted or sponsored by the NIH, interests in these organizations are likely to pose ethics concerns for NIH employees similar to those presented by the entities specifically listed in paragraph (b)(8)(i). This authority might be used, for example, to cover a food, beverage, or tobacco manufacturer, if its products became a pervasive subject of NIH research activities into the health benefits or detriment associated with the product or its ingredients, and the research activities required a substantial coordinated effort across institutes and centers, such that it would be necessary or appropriate to apply a prophylactic rule applicable to all NIH employees. Lists of organizations designated as substantially affected organizations under paragraph (b)(8)(iii) will be maintained by the designated agency ethics official and the NIH deputy ethics counselor and disseminated to employees through appropriate means, including website posting.

A "supported research institution" is defined in paragraph (b)(9) as an educational institution or a non-profit independent research institute that within the last year or currently has applied for, proposed, or received an NIH grant, cooperative agreement, research and development contract, or CRADA.

Employees are also prohibited under paragraph (c)(1) from engaging in any self-employed business activity that involves the sale or promotion of products or services of a substantially affected organization or a health care provider or insurer. This section excepts the ownership of a patent or related commercialization activities conducted pursuant to Executive Order 10096, the Federal Technology Transfer Act of 1986 (FTTA), 15 U.S.C. 3710d, or implementing regulations at 37 CFR 404, as amended. Those activities will continue to be reviewed and approved on a case-by-case basis in accordance with existing conflict of interest and other applicable rules and policies. For example, under the FTTA the NIH might allow an employee inventor to obtain, or retain, title to an NIH invention, because the NIH has determined that it does not wish to file for a patent or otherwise commercialize the invention. The activities of owning that invention in a personal capacity, seeking and owning patent protection on that invention in a personal capacity, and engaging in commercialization activities related to that invention have been encouraged under the FTTA, and are not automatically prohibited by this regulation. Instead, these activities will continue to be scrutinized in accordance with the facts of each situation to determine whether they present a conflict or potential conflict and the situation should be managed to best serve the public interest.

These prohibited outside activities rules are applicable to all NIH employees, but are focused on those types of activities and external entities that may pose the most significant risk of potential conflicts. In addition, the need for prophylactic rules barring certain types of outside activities derives from the considerable complexity of the current regulatory scheme, the intractable difficulties encountered at NIH in differentiating

scientific work performed as an official duty from that proposed as an outside activity, and the significant administrative burden inherent in case-by-case determinations.

The outside activity prior approval process is complicated. The following discourse describes the analysis required for each potential outside activity: Approval requires an assessment of whether the proposed outside activity violates any statute or regulation, including the OGE Standards of Ethical Conduct for Employees of the Executive Branch or the HHS Supplemental Ethics Regulation. Included in the OGE Standards is the requirement that the proposed outside activity cannot create an actual or apparent conflict that would result in recusals that would materially impair an employee's ability to do his job.

In evaluating outside activities for conflicts, the reviewer initially addresses two provisions that form the core of Federal ethics law. A criminal statute, 18 U.S.C. 208, deals with an "actual conflict" due to the employee's own or imputed financial interest in the resolution of a government matter. A regulatory provision in the OGE Standards, 5 CFR 2635.502, principally addresses disqualifications called for when an "appearance of a conflict" arises from a "covered relationship."

Under section 208 of the criminal code, to avoid a conflict of interest that results from outside employment, among other types of financial interests, a Federal employee must not participate personally and substantially in a particular matter that, to his knowledge, directly and predictably affects his own financial interest in the employment opportunity or the financial interests of his outside employer. To prevent an "appearance of a conflict" that results from serving in a role short of employment, for example, as an

advisor, consultant, or other type of independent contractor compensated with fees and expenses, a different rule applies. Under section 502 of the regulations, if a reasonable person with knowledge of the relevant facts would question the Federal employee's impartiality, the employee must recuse, but only from "particular matters involving specific parties," such as grants, contracts, applications, clinical trials, audits, investigations, or lawsuits that involve, as a party or representative of a party, the company to which the employee is providing consulting services.

Both sections are disqualification provisions in that they do not prohibit the acquisition of an employment or consulting relationship, rather they bar actual "participation" in a potentially conflicting matter, either personally or through the direct and active supervision of the participation of a subordinate. However, neither section is triggered by mere knowledge of, or official responsibility for, a particular matter. In short, if an employee can recuse appropriately and still be able to perform the duties of his position, then an outside activity may be approved, provided there are no other statutory or regulatory impediments.

A number of statutes and regulations preclude certain outside activities. For example, if an employee seeks approval to be a lobbyist before the Federal Government, the anti-representation statutes, 18 U.S.C. 203 and 205, would be implicated. If the activity is clearly one that should be done as an official duty, such as an official speech on agency programs, then approval would be denied, under 18 U.S.C. 209, as an improper salary supplementation.

If the circumstances would create an appearance of violating ethical standards, for example where the employee appears to have used his official position to obtain an

outside compensated business opportunity or his actions reasonably create the impression of using his public office for the private gain of the outside company, then under the principles in the OGE Standards, 5 CFR 2635.101(b), and the rules governing misuse of position, 5 CFR 2635.702, the outside activity may be denied. An arrangement for compensation that far exceeds a market rate or that involves first class or foreign travel or extravagant accommodations, for example, may create the appearance that the offer was made or the remuneration was enhanced due to the employee's official position. Another situation cited in the OGE Standards in example 2 following 5 CFR 2635.802 would be where an employee was recently instrumental in formulating industry standards and will again be so involved. If an affected company offers a consulting contract to the employee to render advice to the company about how it can restructure its operations to comply with the very industry standards that the employee has just drafted, the consulting arrangement should not be approved even though the employee lacks any current assignments affecting the industry, and even though the outside consulting can be finished before he again works on such matters.

Another regulation, 5 CFR 2635.807, precludes compensation, subject to certain exceptions, if an employee wants to teach a course, deliver a speech, or write a book that relates to his official duties. (Consulting, technically, is not covered by this section, but the analysis in section 807 does provide guidance in evaluating many outside activities.) The "relatedness" test evaluates, among other factors, the subject matter of the activity. For career employees, compensation is precluded if the teaching, speaking, or writing deals in <u>significant</u> part with any current assignment (or one completed within the last

year) or any ongoing policy, program, or operation of the agency. However, in a note following the provision, OGE observes that a career employee may receive compensation for "teaching, speaking, or writing on a subject within the employee's discipline or inherent area of expertise based on his educational background or experience even though the [activity] deals generally with a subject within the agency's areas of responsibility." But this textual note does not lessen the applicability of other requirements of section 807, notably that the invitation to engage in the activity must not have been extended to the employee primarily because of his official position or tendered, directly or indirectly, by a person or entity that has interests that may be affected substantially by the performance or nonperformance of the employee's official duties. The circumstances of the invitation and the identity of the inviter are as important as the subject matter of the activity.

Determining whether an invitation was prompted by official position requires an inquiry into whether the invitation to participate in the outside activity would not have been forthcoming had the employee not held the status, authority, or duties associated with the employee's Federal position. Resolving whether the inviter has interests that may be affected substantially by the performance or nonperformance of the employee's official duties depends upon whether it is reasonable to assume that the invitee may become involved in a matter substantially affecting the inviter, or whether the chance of such intervention is simply a remote and speculative possibility. These judgments are at times difficult and capable of reasonable debate.

Ascertaining whether the subject matter of the proposed activity deals significantly with a current or recent assignment often may be particularly difficult given

the technical scientific nature of the research conducted or funded by the NIH. For example, only a trained expert could discern whether a scientist engaged in basic research on the molecular basis for the development of skin cancer could be approved to lecture for compensation on the etiology of acute lymphocytic leukemia. The analysis would focus on whether the presenter, in discussing the latter subject, would draw substantially on the knowledge gleaned from the former. Parsing through biomedical jargon to exclude the possibility of a significant overlap is not a task to which the current NIH ethics program is well-suited.

This analytical framework is comprised of requirements that apply across the executive branch. While the framework may be capable of being applied readily at other agencies, historically NIH has confronted unique challenges in implementing these executive branch-wide requirements. In its recent review of the NIH ethics program, OGE noted that, in examining outside activity requests, its reviewers generally were not in a position to identify potential conflict of interest situations because a lack of scientific expertise prevented them from determining how the employees' official duties may have related to their outside consulting activities. The Office of Government Ethics observed that a case-by-case approach utilizing the executive branch-wide standards has not been adequate to protect the reputation of the NIH and its employees. It strongly recommended that the Department develop supplemental regulations to address the kinds of consulting activities that have raised integrity concerns at the NIH.

This rule in fact expands upon that recommendation by addressing other activities that may pose similar concerns. Compensated teaching, speaking, and writing activities

when performed by an NIH scientist for a substantially affected organization or a supported research institution can be no less troubling to the public than employment or consulting with these entities. Where biomedical research and publication activities are involved, any financial connection to affected industries may be perceived adversely. The British charitable trust, Sense About Science, in a recent working paper on scientific peer review observed this phenomenon in the context of sponsored research, stating that often "critical commentators simply emphasi[z]e the source of research funding in order to imply that the researcher's findings may be unreliable in some unspecified way." Sense About Science, Peer Review and the Acceptance of New Scientific Ideas (2004), p. 18, available at www.senseaboutscience.org.uk/.

For the NIH, section 807 does not adequately address this problem. Steps have been taken to incorporate review by a panel of technical advisors into the outside activity approval process in order to verify that the subject matter of a proposed activity is not related to official duties within the meaning of section 807. Efforts to augment training and guidance on the section have been initiated, and additional staff resources have been committed to its implementation. However, neither the addition of scientific expertise, nor training, nor improved administration can avoid the result that section 807 at times permits activities that members of the public might intuitively suppose are prohibited. For example, under current law, an NIH intramural researcher who proposes to deliver a paid lecture on general scientific topics within her inherent area of expertise for a drug company or a grantee university potentially may be allowed to do so if the various tests under section 807 and other applicable provisions are satisfied. Explanations–such as the

lecture would not focus on any current or recent research; or the drug company did not have a product affected by her research; or although the university received a grant from her institute, she was not responsible for extramural funding decisions–may be perceived as legal technicalities.

Section 5501.109(c)(1)(ii) addresses this inherent perception problem and solves the difficulty of evaluating scientific content under the "relatedness" test by targeting the prohibition to those sources of compensation for teaching, speaking, and writing activities that are most directly connected to these identified problems, i.e., substantially affected organizations, supported research institutions, health care providers or insurers, or related trade, professional, or similar associations. These sources of compensation by definition have interests that are affected by NIH programs, policies, and operations and may be perceived as exerting influence on an employee's governmental actions whenever a financial relationship exists. Recent press accounts alleging NIH employee participation as compensated industry spokespersons or as authors of articles or other presentations that purport to endorse the benefits of specific products highlight this concern. Moreover, these entities, whether in industry or academia, are among those most likely to ask an NIH employee to speak or write on technical subjects related to their official duties, thus presenting the analytical quandary previously described when applying the "subject matter" part of the "relatedness" test in section 807.

Although stringent limitations on outside activities have been imposed, the Department is especially mindful of the need for substantive interaction within the scientific community. As the National Academy of Sciences has stated:

> [S]cience is inherently a social enterprise—in sharp contrast to a popular stereotype of science as a lonely, isolated search for the truth. With few exceptions, scientific research cannot be done without drawing on the work of others or collaborating with others. ... The object of research is to extend human knowledge of the physical, biological, or social world beyond what is already known. But an individual's knowledge properly enters the domain of science only after it is presented to others in such a fashion that they can independently judge its validity. This process occurs in many different ways. Researchers talk to their colleagues and supervisors in laboratories, in hallways, and over the telephone. They trade data and speculations over computer networks. They give presentations at seminars and conferences. They write up their results and send them to scientific journals, which in turn send the papers to be scrutinized by reviewers. After a paper is published or a finding is presented, it is judged by other scientists in the context of what they already know from other sources. Throughout this continuum of discussion and deliberation the ideas of individuals are collectively judged, sorted, and selectively incorporated into the consensual but ever evolving scientific world view. In the process, individual knowledge is gradually converted into generally accepted knowledge. ... The social mechanisms of science do more than validate what comes to be known as scientific knowledge. They also help generate and sustain the body of experimental techniques, social conventions, and other "methods" that scientists use in doing and reporting research. ... Because they reflect socially accepted standards in science, their application is a key element of responsible scientific practice.

National Academy of Sciences, On Being a Scientist. (Washington, D.C.: National Academy Press, 1994). Therefore, it is important to observe that the impact of the regulatory ban on outside activities is mitigated in several significant respects, through a transition period, a waiver provision, textual exceptions, and future actions that the Department has committed to undertake.

First, the prohibition provides for a grace period to allow employees responsibly to conclude outstanding obligations. Employees may continue to engage in outside activities that would otherwise be prohibited for a period not to exceed 30 days from the

effective date of the rule, and extensions of time for a maximum of 90 days from the effective date may be granted for good cause.

Second, a process exists under § 5501.106(e) for the designated agency ethics official to waive the application of the across-the-board rule in appropriate circumstances.

Third, as to the teaching, speaking, writing, and editing restrictions, it should be stressed that the ban reaches only compensated activities; travel reimbursement will be permitted.

Fourth, the NIH has determined that current policies and practices governing permissible official duty activities involving speaking or lecturing should be revised. Consequently, the NIH has decided to develop means to ensure that NIH scientists' knowledge continues to be conveyed to the scientific community at large. The NIH will act administratively to accommodate, as official duty activities, those speaking opportunities that might previously have been considered less directly connected to agency mission. The NIH will consider expanding the availability of scientists to appear before relevant audiences and organizations at government expense, when appropriate, or through agency acceptance of travel reimbursement from non-Federal sources under 31 U.S.C. 1353, where permitted.

Fifth, the regulations contain exceptions designed to facilitate professional obligations and certain academic endeavors. These exceptions partially lift the absolute bar on outside activities with supported research institutions and other organizations (except substantially affected organizations) described in § 5501.109(c)(1), but they do not affirmatively permit an activity that would otherwise violate Federal law or

regulations, including 5 CFR parts 2635, 2636, and 5501. Specifically, exceptions are provided that will allow participation in pursuits that are critical to maintaining technical proficiency, professional licenses, and academic credentials and disseminating scientific information, such as teaching involving multiple presentations at academic institutions, providing individual patient care, moderating or presenting at continuing professional education programs, and writing or editing scientific articles, textbooks, and treatises that are subjected to scientific peer review or a substantially equivalent editorial review process. The rule also contains exceptions for employment with, providing professional or consultative services to, or teaching, speaking, writing, or editing for, a political, religious, social, fraternal, or recreational organization. The rule also recognizes that individuals may be employed in non-problematic roles with outside entities such as providing clerical assistance, janitorial services, or unskilled labor.

The exception for moderating or speaking at continuing professional education programs extends not only to sessions conducted for members of professions that impose licensure and program accreditation requirements, but includes events at which scientists, such as chemists or microbiologists, gather to share new insights and findings in their respective fields, provided that the educational events are substantially equivalent to those frequented by their professionally licensed colleagues.

The licensing and program accreditation infrastructure established by certain learned professions generally has not been adopted by doctorates in scientific research. Most professional groups have promulgated standards for their educational programs that are designed to avoid conflicts, commercial promotion, and control by industry sponsors.

See, for example, American College of Surgeons Guidelines for Collaboration of Industry and Surgical Organizations in Support of Research and Continuing Education, available at www.facs.org/fellows_info/statements/st-36.html; American Society of Consultant Pharmacists Guidelines for Industry Support of ASCP Educational Activities, available at www.ascp.com/public/pr/guidelines/indsupp.shtml; and the discussion generally in the Food and Drug Administration publication entitled "Final Guidance on Industry-Supported Scientific and Educational Activities; Notice" at 62 FR 64074, Dec. 3, 1997. These groups police educational activities at which NIH employees may be asked to speak through strict policies limiting industry support to unrestricted educational grants. To provide a similar assurance in all contexts, including at gatherings convened by scientists and researchers from various academic disciplines, the regulations explicitly negate the exception if a substantially affected organization plays a role other than that of a donor of an unrestricted educational grant.

In addition, in order to ensure that the exception is limited to continuing professional education or similar programs, as intended, and not interpreted to encompass every speaking occasion that has some educational content or instructional benefit, the regulation confines the exception to accredited programs or, in the case of a profession or academic discipline whose members are not subject to licensure and which does not have program accreditation requirements, an education program determined by the designated agency ethics official or his designee or, in consultation with the designated agency ethics official or his designee, the NIH Director or the NIH Director's designee to be substantially equivalent to an accredited continuing professional education program.

In determining substantial equivalency for these purposes, a number of factors may be considered. Among them would be whether the education program is sponsored by a regional, national, or international organization that serves the interests of scientists or researchers in a specific discipline (e.g., neuroscientists or experimental biologists). Another attribute would be whether, as part of its mission, the program sponsor has a stated goal of ensuring that audience members remain current with respect to the latest scientific developments in their field of interest. Also important is the extent to which the sponsor regularly holds meetings that attract presenters and panel participants who are renowned for their expertise in the topics covered. Similarly critical is whether the education program is characterized by sufficient academic rigor and known within the scientific community as a venue that enables scientists to disseminate and exchange the latest information, particularly, among different sub-disciplines (e.g., inorganic chemistry as opposed to organic chemistry). An education program conducted by a well established sponsor that has a longstanding reputation for presenting refereed papers and other scientific discourse of high caliber and which attracts, from around the globe, attendees of diverse viewpoints within the relevant discipline would be the paradigm.

The regulation includes an exception for writing activities subjected to scientific peer review or substantially equivalent editorial processes. Scientific peer review is commonly understood in principle, with the primary purposes being to "evaluate scientific and technical merit," "screen for obvious errors in methodology and reasoning," and "ensure that the research is novel and 'important'" within the relevant discipline. Effie J. Chan, Note, The "Brave New World" of Daubert: True Peer Review, Editorial

Peer Review, and Scientific Validity, 70 N.Y.U. L. Rev. 100, 119 n.121 (1995). The concept of scientific peer review also generally involves the application of standards governing scientific misconduct and research integrity. E.g., International Committee of Medical Journal Editors, Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication (2004), available at http://www.icmje.org. HHS recognizes that actual editorial processes may vary in practice, for example, in terms of number of levels of review and the extent to which the publisher or journal relies on outside reviewers. Therefore, the exception is intended to cover writings subjected to any scientific peer review or substantially equivalent processes that are designed to ensure that the material disseminated is scientifically accurate, has technical merit, demonstrates originality, evinces an important contribution to the body of knowledge, and adheres to research and scientific conduct standards generally accepted within the relevant discipline.

Section 5501.110 Prohibited financial interests applicable to employees of the National Institutes of Health

New § 5501.110 creates, for employees of the NIH who file either a public or confidential financial disclosure report, a prohibited financial holdings regulation that bars owning a financial interest, such as stock, in substantially affected organizations. In accordance with 5 CFR 2635.403(a), the Department has determined that the acquisition or holding of these financial interests would cause a reasonable person to question the impartiality or objectivity with which NIH programs are administered.

Public and confidential filers by definition are senior officials or other employees whose duties involve the exercise of significant discretion in certain critical areas of agency operations. Section 5501.110 is similar to an existing financial holdings restriction applied to FDA employees that dates back to 1972. The current version of the restriction applicable to FDA employees was part of the HHS Supplemental Ethics Regulation as it was first issued in 1996, and is found at § 5501.104. Since the enactment of the HHS Supplement, the work of the NIH has been determined to pose similar unique challenges for the agency ethics program. NIH employees, like FDA employees, participate in particular matters that substantially affect significant sectors of the United States economy, in particular, the pharmaceutical, medical device, and biotechnology industries. Even the food and beverage sector that is more associated with the FDA has begun to come within the NIH sphere through research on obesity and other diet-related conditions. Many NIH employees have access to confidential commercial information and trade secrets, the misuse of which can have serious financial consequences. Unethical conduct in this context, including misuse of information, could have serious public health consequences. In sum, the NIH has a compelling need to monitor, and impose reasonable prophylactic restrictions on, the financial ties between NIH employees and the vast number of entities that are substantially affected by NIH programs.

Therefore, § 5501.110 creates a prohibited financial holdings rule that serves the above-described interests and relieves the NIH of the significant administrative burden of resolving many conflict of interest problems on a case-by-case basis. However, § 5501.110 is narrowly tailored in three important respects. First, § 5501.110

distinguishes between interests in organizations that are substantially affected by NIH programs, policies, or operations, i.e., those organizations principally involved in the pharmaceutical and biotechnology industries, and those interests that are not in such organizations. Second, § 5501.110 imposes the strictest limitations on employees whose duties carry the greatest potential for conflict of interest, i.e., those employees who are required to file either a public financial disclosure statement or a confidential financial disclosure statement, pursuant to 5 CFR part 2634. Third, § 5501.110 incorporates a mechanism to exclude certain confidential filers or classes of confidential filers from the prohibited holdings requirement if the across-the-board prohibition is deemed unnecessary to ensure public confidence in the integrity of agency operations and their positions do not fall in certain enumerated categories nor entail responsibilities that are likely to pose conflicts related to financial holdings.

While the new rule prohibits public and confidential filers at the NIH from holding or acquiring any interest in a substantially affected organization, all other NIH employees (as well as those confidential filers excluded from coverage by the rule) will be subject to a $15,000 limit on the holding or acquisition of such interests and certain other restrictions. Currently, in order to avoid a conflict of interest, these employees must monitor their work activities and know the identity and value of their holdings at any given moment. A regulatory exemption at 5 CFR 2640.202 allows employees to work on specific party matters, such as contracts, grants, investigations, or clinical trials, as long as the value of the affected stocks does not exceed $15,000, and on a general matter, such as rulemaking or policy determination, if the value of any one affected holding does

not exceed $25,000, subject to a $50,000 cap when cumulating all affected interests. However, if the asset value exceeds these thresholds, employees must recuse from official participation in particular matters that would have a direct and predictable effect on the financial interests of the companies in which they are invested. These monitoring and recusal responsibilities are exacerbated by the increasing number of mergers, acquisitions, joint ventures, partnerships, intellectual property licensing agreements, and even name changes, particularly within the biotechnology and pharmaceutical industries that, on any given day, may make it difficult to know whether one has a conflict to avoid. By imposing a $15,000 cap on such holdings, the employee, the NIH, and the public can be better assured that the participation by NIH employees in their respective work assignments, whether specific or general in scope, does not pose a conflict created by stock holdings. The $15,000 cap will adjust automatically to any change in the de minimis exemption limit for matters involving parties at 5 CFR 2640.202(a).

Although the dollar amounts in the two provisions are linked, substantively they differ in an important respect. Not all financial interests valued at $15,000 or less will be covered by the OGE regulatory exemption. For example, although the NIH exception permits a non-filer to hold a financial interest in a non-publicly traded company (assuming all the other criteria in the section are also satisfied), the OGE regulatory exemption only applies to securities in publicly traded companies or long-term Federal Government or municipal securities. Accordingly, NIH employees are reminded that even though § 5501.110 may allow retention of certain assets that would otherwise be prohibited, the financial interest may nevertheless be problematic under 18 U.S.C. 208.

Absent a regulatory exemption that specifically addresses the financial interest, a recusal, a divestiture, or an individual waiver may be required.

The prohibitions relating to financial interests will apply to the spouses and minor children of NIH employees. Inasmuch as the financial interests of these relatives are imputed to employees and pose identical conflicts concerns, the Department has made the determination, pursuant to 5 CFR 2635.403(a), that there is a direct and appropriate nexus between this prohibition as applied to spouses and minor children and the efficiency of the service. It should be noted, however, that § 5501.110 is not intended to prohibit employment by spouses and minor children in the affected industry sectors, although any actual or apparent conflicts of interests created as to NIH employees by such employment must be resolved under other applicable provisions of 5 CFR part 2635.

Section 5501.110(e)(1) permits the holding of financial interests acquired through employment with a substantially affected organization. This exception is intended to parallel the FDA provision at amended § 5501.104(b)(1) that excepts pensions or other employee benefits derived from employment with a significantly regulated organization. This exception is necessary to facilitate recruitment of qualified scientific and professional personnel, many of whom may have begun their careers in industry. Because NIH employees, as opposed to spouses and minor children of employees, are generally prohibited under § 5501.109 from engaging in current employment with a substantially affected organization, the provision will primarily apply to financial interests acquired through employment prior to joining the agency. However, it may apply in the limited number of instances in which NIH employees are permitted to have a

concurrent employment relationship with a substantially affected organization, such as a clerical position excepted by § 5501.109(c)(3)(iii), that may provide a pension or other employee benefits.

Section 5501.110(e)(2) excepts financial interests in substantially affected organizations that result from holding an interest in certain publicly traded or publicly available investment funds or a widely held pension or similar fund. To qualify for this exception, the fund must not be self-directed and must not have an express policy or practice of concentrating its investments in substantially affected organizations. For example, a widely diversified mutual fund generally would be a permissible holding, even though the fund holds some stocks of substantially affected organizations whereas a sector fund that focuses on the pharmaceutical industry would not.

Furthermore, § 5501.110(e)(3) provides NIH employees with the opportunity to request an individual exception for certain financial interests. Where the employee can demonstrate exceptional circumstances, the NIH may allow an individual to hold a financial interest in a substantially affected organization, provided that the application of the financial interest prohibition is not necessary to ensure public confidence in the impartiality or objectivity with which NIH programs are administered or to avoid a violation of 5 CFR part 2635.

Pursuant to 5 CFR 2635.403(d), an employee shall be given a reasonable period of time, considering the nature of the employee's particular duties and the nature and marketability of the interest, to divest a financial interest prohibited by paragraphs (c) and (d) of this section. Except in cases of unusual hardship, as determined by the NIH deputy

ethics counselor in consultation with the designated agency ethics official or his designee, a reasonable period shall not exceed 90 days from the date divestiture is first required. For those current employees who will be affected immediately by the promulgation of this rule, it is anticipated that individual requests for divestiture periods of up to 180 days will be granted upon an adequate showing of good cause, such as difficulties in disposing of non-publicly traded assets or a significant adverse financial impact on the employee, the company, or the securities market. During any period in which the employee continues to hold the prohibited financial interest, the employee remains subject to the restrictions imposed by subpart D of 5 CFR part 2635.

As specified in 5 CFR 2635.403(e), an employee who is required to sell or otherwise divest a financial interest and thereby incurs a capital gain may be eligible to defer the tax consequences of divestiture under subpart J of 5 CFR part 2634. This special tax treatment is unavailable if the employee fails to comply with the requisite procedures and disposes of the financial interest prior to receiving a certificate of divestiture from the Director of the Office of Government Ethics.

Section 5501.110(g), for the reasons discussed previously in connection with the FDA provision at § 5501.104(c), specifies that the requirement to divest a financial interest prohibited by paragraphs (c) and (d) of this section is not triggered until the due date for reporting prohibited financial interests under the applicable financial disclosure rules in parts 2634 and 5502 of this title.

Section 5501.111 Awards tendered to employees of the National Institutes of Health

Section 5501.111 prohibits senior NIH employees and other employees with

official responsibility for matters affecting donor organizations from accepting certain awards from outside sources. For these purposes, the term "senior employee" includes, among others, the NIH Director and Deputy Director and the Director, Deputy Director, Scientific Director, and Clinical Director of each Institute and Center within NIH. Other employees of equivalent levels of responsibility will be subject to the award prohibition if their positions are comparable in terms of authority or influence over agency programs and operations, and they receive written notification of their designation as a "senior employee" by the designated agency ethics official or the NIH Director. (A list of "senior employees" so designated will be maintained by the designated agency ethics official and the NIH and disseminated through program instructions or manual issuances.) Further, any award permitted under 5 CFR 2635.204(d) that is not prohibited by this section cannot be accepted without prior written approval.

Section 5501.111 will have no impact on any employee's ability to receive an award that consists only of a plaque or certificate or other item with little intrinsic value that is intended solely for presentation purposes. Such items are not deemed to constitute a gift for purposes of the Standards of Ethical Conduct, 5 CFR part 2635. Likewise, an employee would be permitted to accept free attendance and food and other refreshments at an event in which the employee is presented a plaque or certificate or other item with little intrinsic value under circumstances permitted by 5 CFR 2635.204, such as a speaking engagement or widely attended gathering. Moreover, under certain circumstances, an employee may be permitted by the agency to travel at the award donor's expense to an event at which the employee is to be honored. If travel

reimbursement is accepted from a non-Federal source by the employee's agency, under the authority of 31 U.S.C. 1353 and 41 CFR chapter 304, in conjunction with the employee's receipt of an award in recognition of meritorious public service that is related to the employee's official duties, the reimbursement of such expenses to the agency is not a personal gift to the employee and hence not an award or incident of an award for purposes of 5 CFR 2635.204 or this section.

Specifically, § 5501.111(b) mandates that a senior employee will not be permitted to accept a gift with an aggregate market value of more than $200, or that is cash or an investment interest, that is an award or incident to an award given because of the employee's official position or from a prohibited source. Moreover, it provides that an employee, other than a senior employee, cannot accept such a gift from a person, organization, or other donor that: is seeking official action from the employee, any subordinate of the employee, or any agency component or subcomponent under the employee's official responsibility; does business or seeks to do business with any agency component or subcomponent under the employee's official responsibility; conducts activities substantially affected by any agency component or subcomponent under the employee's official responsibility; or is an organization a majority of whose members fall into one of the above categories. In other words, an NIH employee may not accept a cash award or one valued at more than $200 that is tendered by a donor that has matters pending under the employee's official responsibility, either individually or before subordinates in the employee's chain of command, irrespective of whether the matter would ever reach the employee for advice or decision. Thus, as a practical matter, the

rule would not affect the ability of a non-supervisory employee to accept gifts under 5 CFR 2635.204(d), except for the requirement of prior approval. In addition, a supervisor who is not a senior employee would be permitted to accept gifts allowed under 5 CFR 2635.204(d) that are either given to the supervisor because of official position or from a prohibited source of the NIH that has no matters under the supervisor's official responsibility.

Section 5501.111(b) departs from executive branch uniformity with respect to the treatment of awards. It imposes a stricter gift standard by partially limiting the applicability of an exception to the gift restrictions in subpart B of part 2635 of this title. In the preamble to the final rule that established the Standards of Ethical Conduct for Employees of the Executive Branch, OGE expressed concern about using the supplemental ethics regulation process as a means for one agency, for example, to bar all its employees, without regard to the nature of their duties, from accepting anything from a regulated entity. Permitting agencies to change the basic rules would "portend ... an ethics program destined to fall short of meeting the President's goal of a uniform set of standards of conduct for all executive branch employees." 57 FR 35012, Aug. 7, 1992. Specifically, OGE stated as follows:

> Section 2635.105 [of title 5] permits supplemental regulations "which the agency determines are necessary and appropriate, in view of its programs and operations, to fulfill the purposes of this part" and that are "(1) in the form of a supplement ... and (2) in addition to the substantive provisions of this part." The requirement that they be "in addition" means that the basic provisions will apply and that a supplemental regulation can add something more, such as an additional gift exception, but cannot be used to negate or revoke the provisions of this part. The uniformity required by the Executive order cannot be achieved if agencies can pick and choose which provisions they adopt or override.

57 FR 35010, Aug. 7, 1992.

As a result of the high profile research activities conducted and supported by the NIH and the significant contributions by NIH scientists and administrators in their respective fields, these employees are considered for awards by philanthropic foundations, professional associations, industry, academia and others with some frequency. The Blue Ribbon Panel, in particular, observed an increasing number of awards established by universities that have received grants from family funds for this purpose, stating:

> The growth in the number of these awards has been attributed to many factors, including the wish to honor worthy scientists in new and emerging fields and the goal of individuals and charitable organizations to boost their scientific credentials by identifying themselves with and rewarding first-class scientists. Scientists who receive these awards are frequently required to prepare a lecture as an "acceptance speech." The cash prizes for these awards can range from a few hundred to thousands of dollars.

Blue Ribbon Panel Report, p. 51.

Reviewing these awards on a case-by-case basis presents a number of difficulties. Individual award determinations currently require the agency to evaluate the extent to which the award donor has interests that may be substantially affected by the performance or nonperformance of the honoree's official duties. The Acting Director of OGE in a statement on May 18, 2004, before the House Committee on Energy and Commerce Subcommittee on Oversight and Investigations (OGE Statement) established a list of factors for agency officials to consider when providing advice on acceptance of awards, including factors related to whether an office head is likely to become involved in matters substantially affecting the interests of the particular source, and whether the primary

purpose of a payment is to honor the employee for meritorious public service or achievement, or to compensate the employee for services as a speaker. See Statement of Marilyn L. Glynn, Acting Director, OGE, on NIH Ethics Concerns: Consulting Arrangements and Outside Awards Before the Committee on Energy and Commerce Subcommittee on Oversight and Investigations, United States House of Representatives on May 18, 2004, available on the OGE website as an attachment to DAEOGram DO-04-011 at http://www.usoge.gov/pages/daeograms/dgr_files/2004/do04011.html. The reviewer must inquire whether it is reasonable to assume that the honoree may become involved in a matter substantially affecting the interests of the donor, or whether the chance of such intervention is simply a remote and speculative possibility. Moreover, as recognized in the OGE Statement on awards:

> [I]t may not always be immediately apparent to employees and agency officials whether a particular offer from an outside source should be viewed as a gift subject to the awards exception or as compensation for a speaking activity. This is especially true where an employee is offered something of value in connection with a "lectureship" or "lecture award" sponsored by an outside organization. In some instances, it may not be clear whether the real intent of the payment is to honor the employee for meritorious public service or achievement, or to compensate the employee for providing a speech on a subject of interest to the sponsor or the intended audience.

OGE Statement, p. 7.

Although OGE has provided a number of evaluative factors to consider in making these determinations, a bright-line rule relieves the NIH of the significant administrative burden of resolving these issues on a case-by-case basis and avoids the potential for adverse public perception that may arise when civil servants receive payments from

outside sources. The Government generally has a legitimate interest in avoiding even the perception that its decisions are influenced by outside interests. As indicated by recent experience, this interest is particularly acute in an agency that is the "principal steward" of the national investment in biomedical research.

The Department is also mindful of the need to attract and retain preeminent scientists and administrators. As stated by the Blue Ribbon Panel:

> Recognition is a critical incentive for motivating scientists. Awards resulting from the critical evaluation and assessment of an individual's or group's work or career by peers, including distinguished scientists, hold considerable value to the recipients. Awards not only raise the visibility of the scientist, but also enhance the reputation of his or her institution and research area.

Blue Ribbon Panel Report, p. 51. It is important, therefore, to note that the rule bars only the receipt of a gift with an aggregate market value of more than $200, or that is cash or an investment interest, tendered as an award or incident to an award. The intangible honor that inheres in the recognition as an award recipient, where unaccompanied by gifts having a market value or involving cash or cash equivalents, remains an achievable goal unaffected by the prohibition in § 5501.111(b).

Moreover, under § 5501.111(c), the NIH Director (or the Secretary, with respect to awards offered to the NIH Director), with the approval of the designated agency ethics official, may grant a written exception to the prohibition in § 5501.111(b) to permit an employee to accept an award if: (1) the NIH Director determines that acceptance of the gift will further an agency interest because it confers an exceptionally high honor in the fields of medicine or scientific research, for example, the Nobel Prize in Physiology or

Medicine or the Lasker Medical Research Award; (2) absent the prohibition, the employee would have been permitted to accept the gift under 5 CFR part 2635; and (3) the designated agency ethics official determines that the application of the prohibition is not necessary to ensure public confidence in the impartiality or objectivity of NIH programs or to avoid a violation of 5 CFR part 2635.

The rule also specifies that no NIH employee shall accept an award under 5 CFR 2635.204(d) or § 5501.111 unless prior written approval has been granted. The approval must be in accordance with procedures specified by the designated agency ethics official, or with the concurrence of the designated agency ethics official, the NIH Director or the NIH Director's designee. These procedures are not specified in the regulation because the requirements for issuing supplemental standards of conduct do not apply to internal agency procedures for documenting or processing any determination, approval, or other action required by supplemental regulations. 5 CFR 2635.105(c)(2)(ii). Nevertheless, HHS anticipates that such procedures will prescribe a number of steps of review and may take the following form.

First, the award would be pre-screened and evaluated by an independent advisory committee, which would advise on whether the award constitutes a bona fide award given for meritorious public service or achievement as part of an established program of recognition under the criteria specified in the Standards of Ethical Conduct, 5 CFR 2635.204(d)(1)(i) and (ii). In advising whether an award is bona fide for these purposes, the advisory committee would evaluate whether, under all the circumstances, an award program is constituted by the donor primarily to provide gratuitous honorific recognition

of achievement or whether it is primarily compensatory in nature, for example, to obtain a speaker for a lecture, a teacher for a seminar, or a presenter or panelist for a symposium.

Second, if the independent advisory committee advises that the award is part of a bona fide program of recognition for meritorious public service or achievement, the receipt of the award by an individual employee would be submitted for internal peer review by the NIH Ethics Advisory Committee (NEAC) (or other successor body designated by the NIH Director) for its recommendation to the NIH deputy ethics counselor. To be accepted, the award would have to receive an affirmative recommendation by the NEAC. In the case of an award offered to the NIH Director, the Director of the National Cancer Institute, or other political appointee, the recommendation of the NEAC would be forwarded to the designated agency ethics official.

Third, if the independent advisory committee advises that the award is part of a bona fide program of recognition for meritorious public service or achievement and the receipt of the award by an individual employee has been recommended by the NEAC, the NIH deputy ethics counselor (or the designated agency ethics official in the case of an award to the NIH Director, the Director of the National Cancer Institute, or other political appointee) would review the recommendations and could approve the receipt of the award, if it is determined that acceptance of the award is not prohibited by statute or Federal regulation, including 5 CFR part 2635 and this part. The approving official could determine that even where an award meets the above-described criteria, it is in the agency's interest to impose conditions on the employee's acceptance of the award to

ensure public confidence in the impartiality or objectivity of agency programs. Such conditions could include limiting the type, character, or amount of the award or incidents of the award and imposing a period of disqualification greater than the 12-month period described at § 5501.112.

Section 5501.111(d) provides that if an employee accepts an award without prior approval as required by this section, the employee may be required, in addition to any penalty provided by law and applicable regulations, to forfeit the award by returning it to the donor. If an employee accepts a prohibited award, the employee shall be required, in addition to any penalty provided by law and applicable regulations, to: reject the award and instruct the donor to strike the honoree's name from any list of award recipients; remove the recognition from the employee's résumé or curriculum vitae; return any tangible indicia of the recognition to the donor; and forfeit the award by returning it to the donor.

Section 5501.112 One-year disqualification of employees of the National Institutes of Health from certain matters involving an award donor

Section 5501.112 bars any employee who has, within the last year, accepted an award permitted under 5 CFR 2635.204(d) or § 5501.111 from participating in any particular matter involving specific parties in which the donor is or represents a party unless authorized to do so under 5 CFR 2635.502(d). This provision is necessary to protect the public's confidence in the agency's programs by ensuring that agency employees do not participate officially in specific party matters involving any person or entity that has in the recent past given an award to the employee.

B. Supplemental Financial Disclosure Regulations

New part 5502 reinstates an annual reporting requirement for employees with approved outside activities. Its primary purpose is to allow agency management to review an array of approved activities to ensure that employees have complied with applicable laws and regulations, and to ensure that an approved activity continues to meet the standard for approval. For example, where an employee's official duties have changed since an activity was originally approved, or where a company with which an employee has an outside activity has merged with, or been acquired by, another company that can be affected by the employee's official duties, the agency would need to reevaluate a previously approved activity. The annual reporting requirement is intended to facilitate that review and ensure that changed circumstances do not render a previously approved activity improper.

Prior to 1996, the Department, pursuant to 45 CFR 73.735-709, required employees to submit a report of outside activities on an HHS Form 521 by September 10 of each year with respect to the previous 12 months ending August 31. The HHS Standards of Conduct Regulations at 45 CFR part 73 were largely superseded by the OGE executive branch-wide rules on financial disclosure, 5 CFR part 2634, and employee conduct, 5 CFR part 2635. The OGE regulations permitted agencies to promulgate regulations that would supplement each part, pursuant to 5 CFR 2634.103 and 2635.105. However, at the time the HHS Supplemental Ethics Regulation was issued, the Department did not draft a supplemental provision to carry forward the annual outside

activity reporting requirement. The submission of one outside activity request form, HHS Form 520, was considered sufficient to screen for conflicts and to educate the employee about potential ethical concerns. To meet paperwork reduction goals, the annual filing of an outside activity report was discontinued.

In the preamble discussion of the outside activity prior approval requirement in 5 CFR 5501.106(d), the Department stated as follows:

> The Department will continue to employ HHS Form 520 as both a prior approval request form and a record of the disposition by the approval official. ... No provision is made in these regulations, however, for an annual reporting of outside activities submitted on HHS Form 521, as previously required by 45 CFR 73.735–709. That section elicited an annual written verification whether the work or activity described in the original request was actually performed and required the employee to specify the amount of time spent and whether the activity would continue unchanged. Because the HHS Form 520 contains a blank for specifying duration and any substantive change in the scope of the approved activity would constitute a new activity requiring submission of another HHS Form 520, the annual report appears to be unnecessarily duplicative. Moreover, the information requested would, in any event, form the basis of a responsible dialogue between employees and supervisors concerning workload allocation and the avoidance of conflicts. The minimal benefit to be derived from an annual report does not outweigh the considerable burden involved in collecting, tracking, and reviewing the forms. Accordingly, the requirement for filing an annual HHS Form 521 expires upon the effective date of this rule.

61 FR 39762 (July 30, 1996).

Developments, both technological and otherwise, since that time now tip the scale of burdens and benefits differently. Although the burden on both the agency and its employees remains significant, advances in computer software have reduced this concern considerably. Electronically fillable forms and document tracking programs facilitate the process to a degree not previously attainable. Given the nature of any cumulative list, it

remains true that the HHS Form 521 annual report of outside activities may duplicate in certain respects the information collected in an employee's original request for prior approval on an HHS Form 520 or listed on a public (SF 278) or confidential (OGE Form 450) financial disclosure report. Moreover, because approval of an outside activity will be effective for only one year under new § 5501.106(d)(5), employees will be required to renew long term activities on an annual basis. Nevertheless, despite the potential for overlap in some cases, a number of compelling reasons support the decision to reinstate the HHS Form 521.

First, not all employees who perform approved outside activities are public or confidential report filers. For these non-filers, the annual report may provide the agency the only opportunity to verify whether and on what terms the employee actually undertook the activity for which approval was requested.

Second, after the HHS 521 was discontinued, the system relied on each employee to file a new approval request whenever a substantive change occurred in the employee's duties or the scope of the approved activity. This expectation may have been unrealistic, especially in light of recent allegations that a number of NIH employees may have failed to submit even initial approval forms for their outside consulting activities. Accordingly, enforcement of the ethics requirements would be improved considerably by placing an annual focus on outside activities where each employee would be individually notified of the outside activity rules, provided blank forms (or directed to an electronic version), and required to submit the necessary information by a date certain, and each supervisor would be engaged actively in the effort.

Third, in a rapidly changing economy, every opportunity to assist employees in screening for potential conflicts is valuable. Employees may have undertaken activities that were approved based on information that subsequently changed in a material way and which may call into question the continuing appropriateness of the activity. For example, due to mergers, acquisitions, and changed business plans, companies not previously engaged in certain activities related to an employee's official duties may become engaged in such activities. Likewise, an employee's official duties change over time, potentially creating a conflict with an outside activity that did not previously exist at the time of the initial request.

Fourth, the information requested on, as well as the statistical data derived from, the annual report will assist the Department in meeting its obligation to evaluate periodically the adequacy and effectiveness of the agency's conduct regulations, financial disclosure systems, and enforcement efforts and to take prompt corrective action to remedy actual or potential conflict of interest situations. See 5 CFR 2638.203(b)(10) and (11).

Section 5502.101 General

Section 5502.101 explains that the regulations in part 5502 apply to all employees of the Department of Health and Human Services and supplement the Executive Branch Financial Disclosure Regulations contained in 5 CFR part 2634. Although the annual report of outside activities required by § 5502.102 excludes special Government employees from its coverage, the part as a whole is intended to apply to all employees,

unless otherwise noted. The section is drafted in this manner to accommodate any subsequent supplemental financial disclosure requirements that may be promulgated.

In addition, any regulation in part 5502 that is made applicable to employees of an HHS component designated as a separate agency under § 5501.102(a) applies to employees in a division or region of the Office of the General Counsel that principally advises or represents that component.

Section 5502.102 Annual supplemental report of outside employment or activities

Section 5502.102 requires that employees, other than special Government employees, must file an annual report on or before February 28 of each year with respect to all outside activities that were approved during the prior calendar year (including activities originally undertaken in prior years and reapproved in the preceding calendar year). The report also solicits information of employees who have actually performed an outside activity for which prior approval is required under part 5501, regardless of whether the employees actually obtained such approval.

Section 5502.103 Content of supplemental reports

Section 5502.103 specifies that, in addition to basic identifying information, the annual report must include: a list of all outside activities for which prior approval is required under part 5501 that were approved pursuant to 5 CFR 5501.106(d) or undertaken within the reporting period; a statement as to whether the anticipated work described in a previously approved activity request was actually performed for the person

or organization named in the request; for each outside activity actually performed, the beginning date of the relationship, the date(s) personal services were provided, the total number of hours spent and leave used on the activity, and the ending date of the activity; for ongoing activities, a statement as to how long the activity is anticipated to continue; the type and amount of income and/or reimbursements actually received during the reporting period and the date paid, or which were not received during the reporting period and remain due; a statement as to whether any changes occurred or are anticipated with respect to information supplied in the original outside activity request; a description of any change in the nature, scope or subject matter of any approved activity; and a description of any change in the employee's job, duties, or responsibilities that occurred after the outside activity was approved.

5502.104 Confidentiality of reports

Pursuant to § 107(a)(2) of the Ethics in Government Act, the reports filed pursuant to this part are confidential and any information required to be provided shall not be disclosed to the public. The OGE implementing regulations at 5 CFR 2634.901 specify that this requirement applies to supplemental financial information requested of individuals who file public financial disclosure reports, as well as the information supplied by confidential filers and non-filers. Section 2634.901(d) further states that the statute leaves no discretion on this issue with the agencies. These reports are covered under the OGE/GOVT-2 Government-wide executive branch Privacy Act system of records, as well as any applicable agency records system.

5502.105 Agency procedures

Implementing procedures for the submission and review of any report filed under this part may be prescribed by the designated agency ethics official or, with the concurrence of the designated agency ethics official, any HHS component. These procedures may provide for an extension or several extensions of the due date for any report filed under this part, for good cause shown, totaling not more than 90 days.

5502.106 Supplemental disclosure of prohibited financial interests applicable to employees of the Food and Drug Administration and the National Institutes of Health

Section 5502.106 requires FDA and NIH employees to report prohibited financial interests, including those interests that are covered by an applicable exception, within 30 days of joining the agency, being reassigned from another part of HHS, or acquiring such interests, for example, through marriage, gift, or inheritance. New entrant public and confidential filers who report such interests on their initial SF 278 or OGE 450 financial disclosure forms are not required to submit an additional report under this section. Incumbent public and confidential filers and non-filers are subject to the 30-day reporting requirement whenever a triggering event occurs. Current NIH employees newly subject to this requirement initially will have 60 days from the effective date of the rule to file.

This section is intended to implement the prohibited financial interest provisions applicable to FDA and NIH employees in 5 CFR 5501.104(a), 5501.110(c), and 5501.110(d), by requiring immediate disclosure of these holdings. Absent such reports, prohibited financial interests involuntarily acquired by incumbent public and confidential

filers or held by filers transferred from other components may not be identified until they are disclosed in the annual reporting cycles, after several months or a year or more has passed. The prohibited financial interests of non-filers would escape detection altogether, thus making the $15,000 cap on such holdings largely unenforceable. Prior to the issuance of the HHS Supplemental Ethics Regulation in 1996, the FDA required non-filers to certify that no prohibited financial interests above the de minimis amount were held. Since that time, non-filers sometimes have been in violation of the prohibited holdings regulation because they are not subject to a specific reporting requirement.

At the same time, the agency recognizes that employees, especially in the case of new entrant employees, need a 30-day period in which to investigate their financial holdings and determine which of their interests are prohibited by the agency. The need for such a 30-day period is implicit in the regulations at 5 CFR 2634.201 and 2634.903, which provide new entrant public or confidential filers 30 days in which to submit their financial disclosure reports.

III. Matters of Regulatory Procedure

Administrative Procedure Act

These amendments prescribe rules of agency management or personnel that are exempt under 5 U.S.C. 553(a)(2) from the requirement for notice and comment rulemaking. These amendments also prescribe rules of agency practice and procedure governing employee conduct that are exempt under 5 U.S.C. 553(b) from the requirement of public notice and comment prior to promulgation of a final rule. In addition, with

respect to NIH employees newly subject to restrictions on outside activities, financial holdings, and awards, the persons subject thereto have been provided actual notice of the substance of the rule or a description of the subjects and issues involved. The steps taken that apprise these employees are recounted below.

The need for supplemental regulations to address NIH ethics issues was discussed in public hearings before the United States Senate, Committee on Appropriations, Subcommittee on Labor, Health and Human Services, Education and Related Agencies on January 22, 2004. The NIH Director convened a Blue Ribbon Panel (BRP) in March 2004 and charged the panel to review the existing laws, regulations, policies, and procedures under which the NIH currently operates regarding: (1) real and apparent financial conflicts of interest of NIH staff where compensation or financial benefit from outside sources is received, including consulting arrangements and outside awards; and (2) requirements and policies for the reporting of NIH staff's financial interests, including which interests are subject to public disclosure, and what portion of NIH staff file public disclosures. The BRP was directed to make recommendations for improving existing laws, regulations, policies, and procedures, as appropriate, to the Advisory Committee to the Director, NIH, for deliberation and final recommendations to the NIH Director.

NIH employees were invited to give testimony to the panel, and on March 12, 13 and April 1, 5, 2004, the BRP received such oral and written testimony. Also, an electronic forum was establish in March 2004 to collect input from intramural scientists for the BRP's consideration. In the end, over 300 NIH employees gave comments to the BRP from March to April, 2004.

The BRP presented its findings to the Advisory Committee to the Director at an open meeting on May 6, 2004. In addition, the BRP Co-Chairs presented the panel's findings to the United States House of Representatives, Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, on May 12, 2004.

At the June 22, 2004, hearing of the Oversight and Investigations Subcommittee, the NIH Director announced his intention to seek supplemental ethics regulations in three areas: outside activities, prohibited financial holdings, and awards. These proposals were developed after intensive internal reviews of NIH's ethics rules and procedures, and based, in part, on recommendations from the BRP. Immediately following the hearing, on June 23, 2004, the NIH produced talking points summarizing the NIH Director's testimony which were circulated to the Directors of the 27 institutes and centers (ICs) that comprise the NIH and to the IC Deputy Ethics Counselors. The talking points equipped NIH leadership to answer inquiries from NIH employees regarding the proposed changes.

The ICs also took action to educate their employees about the proposed changes. On July 20, 2004, the National Cancer Institute, the largest IC, held an all-hands meeting where the Director of the NIH Ethics Office (NEO) presented the proposed changes and answered employees' questions. On July 28, 2004, the Clinical Center held a briefing for its management on the proposed changes where the NEO Director again led the discussion and answered questions.

Starting in early September 2004, the NIH Ethics Advisory Committee, the group established by the NIH Director in January 2004 to provide peer review of outside activity and award approval requests from certain NIH employees, began notifying employees

that the proposed changes may affect their recently approved outside activities. The NEAC notification stated:

> As you know, the NIH is making changes in its ethics program. Some changes, such as the creation of the NIH Ethics Advisory Committee (NEAC), have already been made. Other changes have been proposed.
>
> In this interim period, the current rules still apply, and requests to conduct outside activities are being approved based on these rules. You should note that after the new rules are adopted and take effect, certain types of outside activities, which may currently be approved, may be limited, if not prohibited altogether. For example, in contrast to the current rules, the NIH is considering prohibiting consulting arrangements with grantees for all employees, and not permitting such arrangements with pharmaceuticals and biotechnology companies. Membership on corporate boards and scientific advisory boards may also be banned. Furthermore, compensation in the form of stock or stock options may well be prohibited.
>
> We are giving you this information for planning purposes only. If you receive permission to engage in an outside activity and to receive the corresponding compensation from that activity, you may, of course, proceed with that activity. However, be aware that the rules [with respect] to that activity may change in the near future and that you will be required to change or adapt your activity to those new rules. Please be assured we will do everything we can to keep you apprised of changes to policies and procedures as they occur during this interim period.

On September 24, 2004, the NIH Deputy Director sent an all-employee memorandum via e-mail to notify NIH employees of the agency's plan to seek in effect a one-year moratorium on consulting with pharmaceutical and biotechnology companies. The memorandum explained that this step was being taken to give the NIH "time to complete [its] review of specific cases, develop effective information systems to track outside activities, and develop more effective ethics training programs for staff before a final policy is put in place."

On November 29, 2004, the NIH Director held a town hall meeting for over 180 intramural scientists. At the meeting, the NIH Deputy Director gave an overview of the

various steps that the NIH has taken to revise its ethics program, including a discussion of the proposed regulatory changes.

In addition to the above described steps taken by management to keep NIH employees apprised of the proposed changes to the ethics program, the NIH in March 2004 created a conflict of interest section on its homepage. Employees were notified that up-to-date information on the proposed changes to the ethics program would be posted periodically on the website. Among other informative documents, the NIH posted the BRP's report, the NIH Director's June 22 Subcommittee testimony, and the September 24 notification. Furthermore, the proposed changes received extensive and continuous coverage in various daily newspapers and scientific trade and professional magazines and journals.

To the extent that these internal agency regulations governing employee conduct have an extra-agency impact, the Department of Health and Human Services, pursuant to 5 U.S.C. 553(b)(B), for good cause, finds that providing notice and utilizing public comment procedures prior to promulgation of this interim rule are unnecessary and contrary to the public interest. The issues involved in this rulemaking primarily affect Federal employees. Those external entities that may have an indirect interest in hiring Federal employees, having them own stock, or giving them monetary awards are affected marginally. The primary effect of the prohibitions contained in these regulations is to establish prophylactic rules that preclude certain outside activities, financial holdings, and gifts on a uniform basis where many would have been prohibited as well under a case-by-case determination process.

As noted previously, the ethics issues that have engendered these regulations have been described extensively in many fora. The deliberative process in developing this interim rule has already been informed by input from employees, agency management, and members of the public in hearings before the NIH Blue Ribbon Panel on Conflict of Interest Policies and in testimony before the Senate Committee on Appropriations, Subcommittee on Labor, Health and Human Services, Education and Related Agencies, and the House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations. The public through press accounts and the employees through agency notice have been well aware that Federal regulation on these matters was impending, and an opportunity for their involvement has occurred. NIH employees for nearly a year have faced considerable uncertainty and may have deferred commitments pending the issuance of an anticipated rule. Addressing at this time the ethics issues at the National Institutes of Health is of paramount importance to ensure public confidence in the scientific and health research conducted and funded by that agency and to resolve immediately the uncertainty surrounding employee decisions in these matters. In sum, employing the notice and comment procedures is unnecessary and contrary to the public interest, in part, because equivalent actions have already been taken to inform and involve interested parties and further process would not contribute substantially to the development of the regulation when balanced against the harm that may result from further delay and uncertainty.

Pursuant to 5 U.S.C. 553(d)(3), the Department of Health and Human Services also has determined, for the reasons discussed, that good cause exists for dispensing with the requirement of a 30-day delayed effective date. Those NIH employees who will be

required to terminate their existing outside activities or divest currently held financial interests are provided transitional periods within which to comply. Because the interim revisions predominately affect the NIH ethics program and are critically necessary to preserve the integrity of NIH programs and operations, a delay in the effective date would be contrary to the public interest.

The public interest is instead served by making additional restrictions on the outside activities, financial holdings, and awards of NIH employees effective immediately upon publication (with the exception of transitional grace periods). The integrity of NIH programs has been potentially called into question by public examples of employees' outside activities and other financial ties to industry and grantee institutions. The Department and NIH are committed to correcting these problems through more careful oversight and restrictions that will lessen the potential that real or apparent conflicts may arise from unanticipated or undetected relationships with external organizations. Given that commitment, and the importance of implementing the restrictions as promptly as possible, the best interests of the NIH, the employees, and the public will be served by the immediate effectiveness of this rule.

Those provisions that apply to allowable holdings of FDA employees or gifts received from Indian tribes or Alaska Native villages recognize exemptions or relieve restrictions under current law and thus are effective upon publication pursuant to 5 U.S.C. 553(d)(1). As to other provisions that clarify or update the existing supplemental regulation with respect to nomenclature, agency organization, or procedure, or that document longstanding or other authoritative interpretations, no useful purpose would be served by delaying the effective date for those changes.

Interested persons may submit written comments on this interim final rule. The Department of Health and Human Services will review all comments that are received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER] and consider any modifications to this interim rule that appear warranted before adopting a permanent final rule on this matter.

Regulatory Flexibility Act

The Department of Health and Human Services has determined under the Regulatory Flexibility Act, 5 U.S.C. chapter 6, that this rule will not have a significant economic impact on a substantial number of small entities because the rule prescribes personnel provisions that primarily affect HHS employees.

Paperwork Reduction Act

The Paperwork Reduction Act, 44 U.S.C. chapter 35, does not apply to these final rule amendments because they do not contain information collection requirements that are subject to approval by the Office of Management and Budget.

Congressional Review Act

The Department of Health and Human Services has determined that this rulemaking is not a rule as defined in 5 U.S.C. 804, and, thus, does not require review by Congress. This rulemaking is related to HHS personnel.

Executive Orders 12866 and 12988

Because this rule relates to HHS personnel, it is exempt from the provisions of Executive Orders 12866 and 12988.

List of Subjects

5 CFR Part 5501

Conflict of interests, Ethics, Executive branch standards of conduct, Financial interests, Government employees, Outside activities.

5 CFR Part 5502

Conflict of interests, Ethics, Government employees, Outside activities, Reporting and record keeping requirements.

Dated: January 25, 2005

/s/

Edgar M. Swindell,

Designated Agency Ethics Official, Department of Health and Human Services.

Dated: January 26, 2005

/s/

Wade F. Horn,

Acting Secretary, Department of Health and Human Services.

Approved: January 26, 2005

/s/

Marilyn L. Glynn,

Acting Director, Office of Government Ethics.

■ For the reasons discussed in the preamble, the Department of Health and Human Services, with the concurrence of the Office of Government Ethics, amends chapter XLV of title 5 of the Code of Federal Regulations as follows:

TITLE 5–[AMENDED]

CHAPTER XLV–DEPARTMENT OF HEALTH AND HUMAN SERVICES

PART 5501–SUPPLEMENTAL STANDARDS OF ETHICAL CONDUCT FOR EMPLOYEES OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

■ 1. The authority citation for part 5501 continues to read as follows:

AUTHORITY: 5 U.S.C. 301, 7301, 7353; 5 U.S.C. App. (Ethics in Government Act of 1978); 25 U.S.C. 450i(f); 42 U.S.C. 216; E.O. 12674, 54 FR 15159, 3 CFR, 1989 Comp., p. 215, as modified by E.O. 12731, 55 FR 42547, 3 CFR, 1990 Comp., p. 306; 5 CFR 2635.105, 2635.203, 2635.403, 2635.802, 2635.803.

■ 2. Amend § 5501.101 by revising paragraph (c)(2) to read as follows:

§ 5501.101 General.

* * * * *

(c) * * *

(2) Significantly regulated organization means an organization for which the sales of products regulated by the Food and Drug Administration (FDA) constitute ten percent or more of annual gross sales in the organization's previous fiscal year; where an organization does not have a record of sales of FDA-regulated products, it will be deemed to be significantly regulated if its operations are predominately in fields regulated by FDA, or if its research, development, or other business activities are reasonably expected to result in the development of products that are regulated by FDA.

■ 3. Amend § 5501.102 as follows:

a. Revise the first sentence of paragraph (a) introductory text to read as set forth below;

b. Revise paragraph (a)(3) to read as set forth below;

c. Remove paragraph (a)(7) and redesignate paragraph (a)(6) as (a)(7);

d. Add new paragraph (a)(6) to read as set forth below;

e. Remove paragraph (a)(11) and redesignate paragraphs (a)(12) and (a)(13) as paragraphs (a)(11) and (a)(12);

f. In paragraph (b)(2), remove the word "13" and add in its place, the word "12";

g. Add new paragraph (c)(1)(iii) to read as set forth below.

The additions and revisions read as follows:

§ 5501.102 Designation of HHS components as separate agencies.

(a) Separate agency components of HHS. Pursuant to 5 CFR 2635.203(a), each of the twelve components of HHS listed below is designated as an agency separate from each of the other eleven listed components and, for employees of that component, as an agency distinct from the remainder of HHS. * * *

* * * * *

(3) Agency for Healthcare Research and Quality;

* * * * *

(6) Centers for Medicare and Medicaid Services;

* * * * *

(c) * * *

(1) * * *

(iii) The regulations at § 5501.111 governing the receipt of awards by employees of the National Institutes of Health; and

* * * * *

■ 4. Amend § 5501.103 by revising paragraph (a) to read as follows:

§ 5501.103 Gifts from federally recognized Indian tribes or Alaska Native villages or regional or village corporations.

(a) Tribal or Alaska Native gifts. In addition to the gifts which come within the exceptions set forth in 5 CFR 2635.204, and subject to all provisions of 5 CFR 2635.201 through 2635.205, an employee may accept unsolicited gifts of native artwork, crafts, or other items representative of traditional native culture from federally recognized Indian tribes or Alaska Native villages or regional or village corporations, provided that the aggregate market value of individual gifts received from any one tribe or village under the authority of this paragraph shall not exceed $200 in a calendar year.

* * * * *

■ 5. Amend § 5501.104 by revising the section heading, paragraphs (a), (b)(1), and (b)(2)(i), and designating the note following paragraph (b)(4) as note to paragraph (b) and revising it, and adding new paragraph (c) to read as follows:

§ 5501.104 Prohibited financial interests applicable to employees of the Food and Drug Administration.

(a) General prohibition. Except as permitted by paragraph (b) of this section, no employee or spouse or minor child of an employee, other than a special Government employee or the spouse or minor child of a special Government employee, of the Food and Drug Administration shall have a financial interest in a significantly regulated organization.

(b) * * *

(1) An employee or spouse or minor child of an employee may have a financial interest, such as a pension or other employee benefit, arising from employment with a significantly regulated organization.

NOTE TO PARAGRAPH (b)(1): FDA employees who file public or confidential financial disclosure reports pursuant to 5 CFR part 2634, as opposed to spouses and minor children of such employees, are generally prohibited under § 5501.106(c)(3) from engaging in current employment with a significantly regulated organization.

(2) * * *

(i) The total cost or value, measured at the time of acquisition, of the combined interests of the employee and the employee's spouse and minor children in the regulated organization is equal to or less than the de minimis exemption limit for matters involving parties established by 5 CFR 2640.202(a) or $15,000, whichever is greater (the phrase "time of acquisition" shall mean the date on which the employee actually acquired the financial interest–or on which the financial interest became imputed to the employee under 18 U.S.C. 208–whether by purchase, gift, bequest, marriage, or otherwise, except that with respect to a financial interest that was acquired prior to the employee's entrance on duty as an employee of the Food and Drug Administration, the "time of acquisition" shall be deemed to be the date on which the employee entered on duty);

* * * * *

NOTE TO PARAGRAPH (b): With respect to any excepted financial interest, employees are reminded of their obligations under 5 CFR part 2635, and specifically their obligation under subpart D of part 2635 to disqualify themselves from participating in any particular matter in which they, their spouses or minor children have a financial interest arising from publicly traded securities that exceeds the de minimis thresholds specified in the regulatory exemption at 5 CFR 2640.202 or from non-publicly traded securities that

are not covered by the regulatory exemption. Furthermore, the agency may prohibit or restrict an individual employee from acquiring or holding any financial interest or a class of financial interests based on the agency's determination that the interest creates a substantial conflict with the employee's duties, within the meaning of 5 CFR 2635.403.

(c) Reporting and divestiture. For purposes of determining the divestiture period specified in 5 CFR 2635.403(d), as applied to financial interests prohibited under paragraph (a) of this section, the "date divestiture is first directed" means the date on which the new entrant public or confidential financial disclosure report required by part 2634 of this title or any report required by § 5502.106(c) of this chapter is due.

■ 6. Amend § 5501.106 as follows:

a. Revise paragraph (c)(3) heading and introductory text, paragraphs (c)(4)(i) introductory text and (d)(1)(i) introductory text, and paragraphs (d)(2) heading, (d)(2)(i), (d)(2)(iii), (d)(3), and (d)(4) to read as set forth below;

b. In the first sentence of the note following paragraph (d)(4), remove the duplicate second occurrence of the words "granting of";

c. Redesignate paragraph (d)(5) as paragraph (d)(6) and add new paragraph (d)(5) to read as set forth below; and

d. Add new paragraph (e) to read as set forth below.

The revisions and additions read as follows:

§ 5501.106 Outside employment and other outside activities.

* * * * *

(c) * * *

(3) Prohibited outside activities applicable to employees of the Food and Drug Administration. An employee of the Food and Drug Administration who is required to file a public or confidential financial disclosure report pursuant to 5 CFR part 2634 shall not: * * *

(4) * * *

(i) An employee who serves as an attorney in or under the supervision of the Office of the General Counsel or the Office of Counsel to the Inspector General shall not engage in any outside practice of law that might require the attorney to: * * *

* * * * *

(d) Prior approval for outside employment and other outside activities–(1) General approval requirement. Except to the extent that an employment or other activity has been exempted under paragraph (d)(6) of this section, an employee shall obtain written approval prior to engaging, with or without compensation, in the following outside employment or activities: * * *

(2) Additional approval requirement for employees of the Food and Drug Administration and the National Institutes of Health.

(i) In addition to the general approval requirements set forth in paragraph (d)(1) of this section, an employee of the Food and Drug Administration or the National Institutes of Health shall obtain written approval prior to engaging in any outside employment, as defined in 5 CFR 2635.603(a), whether or not for compensation, or any self-employed business activity.

* * * * *

(iii) The requirement of paragraph (d)(2)(i) of this section shall not apply to the extent that an employment activity has been exempted, pursuant to paragraph (d)(6) of this section.

(3) Submission of requests for approval. (i) An employee seeking to engage in any of the activities for which advance approval is required shall make a written request for approval a reasonable time before beginning the activity. This request shall be directed to the employee's supervisor. The supervisor shall submit the request and a statement addressing the extent to which the employee's duties are related to the proposed outside activity to an agency designee, who shall make a final determination with respect to the request.

(ii) All requests for prior approval shall include the following information:

(A) The employee's name, contact information, organizational location, occupational title, grade, step, salary, appointment type, and financial disclosure filing status;

(B) The nature of the proposed outside employment or other outside activity, including a full description of the specific duties or services to be performed;

(C) A description of the employee's official duties that relate to the proposed activity;

(D) A description of how the employee's official duties will affect the interests of the person for whom the proposed activity will be performed;

(E) The name and address of the person or organization for whom or with which the work or activity will be done, including the location where the services will be performed;

(F) The estimated total time that will be devoted to the activity. If the proposed outside activity is to be performed on a continuing basis, a statement of the estimated number of hours per year; for other employment, a statement of the anticipated beginning and ending date;

(G) A statement as to whether the work can be performed entirely outside of the employee's regular duty hours and, if not, the estimated number of hours and type of leave that will be required;

(H) The method or basis of any compensation to be received (e.g., fee, per diem, honorarium, advance, royalties, stock, stock options, travel and expenses, or other form of remuneration tendered in cash or in-kind in connection with the proposed activity) from the person or organization for whom or with which the work or activity will be done;

(I) The amount of any compensation to be received from the person or organization for whom or with which the work or activity will be done;

(J) The amount and date of any compensation received, or due for services performed, within the six-year period immediately preceding the submission of the request for approval from the person or organization for whom or with which the work or activity will be done (including any amount received or due from an agent, affiliate, parent, subsidiary, or predecessor of the proposed payor);

(K) A statement as to whether the compensation is derived from an HHS grant, contract, cooperative agreement, or other source of HHS funding or attributed to services related to an activity funded by HHS, regardless of the specific source of the compensation;

(L) For activities involving the provision of consultative or professional services, a statement indicating whether the client, employer, or other person on whose behalf the services are performed is receiving, or intends to seek, an HHS grant, contract, cooperative agreement, or other funding relationship;

(M) For activities involving teaching, speaking, or writing, a syllabus, outline, summary, synopsis, draft or similar description of the content and subject matter involved in the course, speech, or written product (including, if available, a copy of the text of any speech) and the proposed text of any disclaimer required by 5 CFR 2635.807(b)(2) or by the instructions or manual issuances authorized under paragraph (d)(6) of this section; and

(N) Such other relevant information that the designated agency ethics official or, with the concurrence of the designated agency ethics official, each of the separate agency components of HHS listed in § 5501.102(a) determines is necessary or appropriate in order to evaluate whether a proposed activity is likely to involve conduct prohibited by statute or Federal regulations, including 5 CFR part 2635 and this part.

(4) Standard for approval. Approval shall be granted only upon a determination that the outside employment or other outside activity is not expected to involve conduct prohibited by statute or Federal regulation, including 5 CFR part 2635 and this part. * * * * * * * * *

(5) Duration of approval. Approval shall be effective for a period not to exceed one year from the date of approval. Upon a significant change in the nature of the outside activity or in the employee's official position or duties, the employee shall submit a

revised request for approval using the procedure in paragraph (d)(3) of this section. If the outside activity is anticipated to exceed one year from the date of the most recent approval, the employee shall renew the request for approval no later than thirty days prior to the expiration of the period authorized.

(e) Waivers. The designated agency ethics official may grant a written waiver from any prohibited outside activity provision in this section or in § 5501.109 based on a determination that the waiver is not inconsistent with part 2635 of this title or otherwise prohibited by law and that, under the particular circumstances, application of the prohibition is not necessary to avoid the appearance of misuse of position or loss of impartiality or otherwise to ensure confidence in the impartiality and objectivity with which agency programs are administered. A waiver under this paragraph may impose appropriate conditions, such as requiring execution of a written disqualification.

■ 7. Add new § 5501.109 to read as follows:

§ 5501.109 Prohibited outside activities applicable to employees of the National Institutes of Health.

(a) Applicability. This section does not apply to special Government employees.

(b) Definitions. For purposes of this section:

(1) Compensation has the meaning set forth in 5 CFR 2635.807(a)(2)(iii).

(2) Continuing professional education means a course, a program, a series of courses or programs, or other educational activity provided to members of a profession, as defined in 5 CFR 2636.305(b)(1), or academic discipline and designed principally to maintain or advance the skills and competence of practitioners in a field of specialized

knowledge and to expand an appreciation and understanding of the professional responsibilities, fiduciary obligations, or ethical aspirations incumbent upon members of the group. For those members of a profession or academic discipline that does not subject its members to licensure or continuing education requirements, the term continuing professional education includes those educational activities that exemplify a purpose and content similar to those offered to or required of members of a licensed profession.

(3) Educational activity provider means a supported research institution, a health care provider or insurer, or a related trade, professional, or similar association that offers accredited continuing professional education (or, in the case of a profession or academic discipline whose members are not subject to licensure and which does not have program accreditation requirements, an education program determined by the designated agency ethics official or his designee or, in consultation with the designated agency ethics official or his designee, the NIH Director or the NIH Director's designee to be substantially equivalent to an accredited continuing professional education program), but does not include a substantially affected organization.

(4) Employment has the meaning specified in 5 CFR 2635.603(a).

(5) Health care provider or insurer means a hospital, clinic, skilled nursing facility, rehabilitation facility, durable medical equipment supplier, home health agency, hospice program, health maintenance organization, managed care organization, or other provider of health care items and services as defined in sections 1877(h)(6) or 1903(w)(7) of the Social Security Act (42 U.S.C. 1395(h)(6) or 1396(w)(7)) and any entity organized

and licensed as a risk-bearing entity eligible to offer health insurance or health benefits coverage.

(6) Related trade, professional, or similar association means a trade, professional, consumer, advocacy, or other organization, association, society, or similar group that is significantly involved in advancing the interests of persons or entities engaged in activities related to or affected by the health, scientific, or health care research conducted or funded by the NIH.

(7) Scientific peer review is the evaluation of scientific research findings for competence, significance, and originality by qualified experts who research and submit work for publication in the same field and which provides systematized accountability for adherence to ethical guidelines commonly accepted within the relevant research community for disseminating scientific information.

(8) Substantially affected organization means:

(i) A biotechnology or pharmaceutical company; a medical device manufacturer; or a corporation, partnership, or other enterprise or entity significantly involved, directly or through subsidiaries, in the research, development, or manufacture of biotechnological, biostatistical, pharmaceutical, or medical devices, equipment, preparations, treatments, or products;

(ii) Any organization a majority of whose members are described in paragraph (b)(8)(i) of this section; and

(iii) Any other organization determined by the designated agency ethics official or, in consultation with the designated agency ethics official, by the NIH Director or the NIH

Director's designee that is substantially affected by the programs, policies, or operations of the NIH.

(9) Supported research institution means any educational institution or non-profit independent research institute that:

(i) Is, or within the last year has been, an applicant for or recipient of an NIH grant, cooperative agreement, or research and development contract;

(ii) Is, or within the last year has been, a proposer of or party to a cooperative research and development agreement (CRADA) with the NIH; or

(iii) Any organization a majority of whose members are described in paragraphs (b)(9)(i) or (ii) of this section.

(10) Unrestricted educational grant means funds received by or available to an educational activity provider from another source that are granted without stipulated conditions for their use other than the limitation that the funds shall be used to advance an educational program of the grant recipient. For purposes of this section, an educational grant shall not be considered unrestricted if the funding source for a continuing professional education program directly or indirectly:

(i) Selects or recommends the moderators, speakers, or presenters at the sponsored event;

(ii) Independently provides additional funding to the moderators, speakers, or presenters in connection with the educational activity;

(iii) Determines or recommends the audience composition;

(iv) Specifies or recommends the topics to be addressed, or

(v) Controls or recommends the planning, content, or implementation of the program in a manner inconsistent with guidelines established by a relevant professional association or accrediting organization that are designed to ensure that such activities are accurate, balanced, educational, free from commercial bias, nonpromotional, and independent of the influence of the funding source.

(11) Unrestricted financial contribution means funds received by or available to a publisher, academic press, editorial board, or other entity affiliated with or operated by a supported research institution, a health care provider or insurer, or a related trade, professional, or similar association from another source that are provided without stipulated conditions for their use other than the limitation that the funds shall be used to advance peer-reviewed writing or editing by the funds recipient. For purposes of this section, a financial contribution shall not be considered unrestricted if the funding source for peer-reviewed writing or editing directly or indirectly:

(i) Selects or recommends the author, reviewer, referee, or editor;

(ii) Independently provides additional funding to the author, reviewer, referee, or editor in connection with the writing or editing activity;

(iii) Determines or recommends the targeted audience of the writing or editing activity;

(iv) Specifies or recommends the topics to be addressed, or

(v) Controls or recommends the planning, content, or distribution of the written or edited product in a manner inconsistent with ethical guidelines commonly accepted within the relevant research community for disseminating scientific information which

are designed to ensure that such writing or editing is accurate, unbiased, nonpromotional, transparent with respect to disclosure of potential conflicts, and independent of the influence of the funding source.

(c) Prohibitions–(1) Prohibited outside activities with substantially affected organizations, supported research institutions, health care providers or insurers, and related trade, professional, or similar associations. Except as permitted by paragraph (c)(3) of this section, an employee of the NIH shall not:

(i) Engage in employment with a substantially affected organization, a supported research institution, a health care provider or insurer, or a related trade, professional, or similar association;

(ii) Teach, speak, write, or edit for compensation for any substantially affected organization, supported research institution, health care provider or insurer, or related trade, professional, or similar association; or

(iii) Engage in any self-employed business activity that involves the sale or promotion of products or services of a substantially affected organization or a health care provider or insurer, except for the purpose of commercializing invention rights obtained by the employee pursuant to Executive Order 10096, 15 U.S.C. 3710d, or implementing regulations.

(2) General exception. Nothing in paragraph (c)(1) of this section prevents an employee from engaging in employment with, or teaching, speaking, writing, or editing for, a political, religious, social, fraternal, or recreational organization.

(3) Specific exceptions. Notwithstanding the prohibitions in paragraph (c)(1) of this section:

(i) Teaching. An employee may engage in and accept compensation for teaching a course requiring multiple presentations as permitted under 5 CFR 2635.807(a)(3).

(ii) Clinical, medical, or health-related professional practice. An employee may engage in and accept compensation for the outside practice of medicine, dentistry, pharmacy, nursing, or similar health-related professional practice that involves the personal provision of care, treatment, or other health-related professional services to or in connection with individual patients, provided that:

(A) The provision of health-related professional services to such individuals is not part of any ongoing research project conducted or funded by the NIH;

(B) The employee does not establish a private practice relationship with a current or recently discharged NIH patient or subject of an NIH-conducted or NIH-funded clinical trial or protocol;

(C) The employee does not personally refer private practice patients to the NIH; and

(D) The professional practice does not involve substantial unrelated non-professional duties, such as personnel management, contracting and purchasing responsibilities (other than "out-of- stock" requisitioning), and does not involve employment by a medical product manufacturer in the conduct of biomedical research.

(iii) Clerical or similar services. An employee may engage in and accept compensation for employment that is limited to clerical or similar services described in § 5501.106(c)(3)(ii)(B).

(iv) Continuing professional education. An employee may engage in and accept

compensation for a teaching, speaking, writing, or editing activity that is unrelated to the employee's official duties within the meaning of 5 CFR 2635.807 if the activity is performed as part of a continuing professional education program conducted by an educational activity provider. If a substantially affected organization provides financial support for a continuing professional education program conducted by an educational activity provider, this exception is inapplicable unless the substantially affected organization is involved only as the funding source for an unrestricted educational grant.

(v) Authorship of writings subjected to scientific peer review or a substantially equivalent editorial review process. An employee may engage in and accept compensation for a writing or editing activity that is unrelated to the employee's official duties within the meaning of 5 CFR 2635.807 if the resulting article, chapter, essay, report, text, or other writing is submitted to a publisher, academic press, editorial board, or other entity affiliated with or operated by a supported research institution, a health care provider or insurer, or a related trade, professional, or similar association for publication in a scientific journal, textbook, or similar publication that subjects manuscripts to scientific peer review or a substantially equivalent editorial review process. If a substantially affected organization funds the publishing activities of a supported research institution, a health care provider or insurer, or a related trade, professional, or similar association, this exception is inapplicable unless the substantially affected organization is involved only as an unrestricted financial contributor and exercises no editorial control.

(4) Transitional grace period. Provided that the activity is not otherwise prohibited by statute or Federal regulation, including 5 CFR part 2635 and this part, and

the employee has obtained prior written approval for the outside activity in accordance with the procedures in § 5501.106(d), an employee may continue to engage in outside activities that would otherwise be prohibited by paragraph (c)(1) of this section for a period not to exceed 30 days from the effective date of this rule. An employee may request additional time up to a maximum of 90 days from the effective date of this rule if:

(i) The outside activity had been reviewed by the NIH Ethics Advisory Committee (NEAC) and subsequently approved by the NIH deputy ethics counselor (DEC) (or, for those activities not within the jurisdiction of the NEAC, if the outside activity had been reviewed by the employee's supervisor and subsequently approved by the DEC for the employee's institute or center) during the period between January 1, 2004, and [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER], the effective date of this rule;

(ii) The employee submits a written request within 30 days of the effective date of this rule seeking authorization to continue the outside activity for such additional time as the employee requests (not to exceed the maximum 90-day grace period authorized by this section);

(iii) The employee demonstrates that additional time is necessary to allow the employee to conclude responsibly his outstanding obligations;

(iv) The NEAC (or, for those activities not within the jurisdiction of the NEAC, the employee's supervisor) finds that good cause exists for permitting an extended grace period beyond the initial 30 days authorized by this section and recommends to the NIH DEC (or the DEC for the employee's institute or center) that an extension be granted; and

(v) The NIH DEC, after consultation with the designated agency ethics official or his designee (or, for those activities not within the jurisdiction of the NEAC, the DEC for the employee's institute or center, after consultation with the NIH DEC or his designee), determines the length of the extension and grants the employee additional time to comply with the outside activity prohibitions in paragraph (c)(1) of this section.

(5) An employee who meets the criteria of paragraphs (c)(4)(i) and (ii) of this section may continue to engage in the outside activity pending the final resolution of the request, but in no event shall such activity continue beyond the 90-day grace period. If the extension request is denied, the employee shall cease the activity no later than five days after the employee receives notice of the denial.

■ 8. Add new § 5501.110 to read as follows:

§ 5501.110 Prohibited financial interests applicable to employees of the National Institutes of Health.

(a) Applicability. This section does not apply to special Government employees or the spouse or minor children of a special Government employee.

(b) Definitions. For purposes of this section:

(1) Confidential filer means an employee of the National Institutes of Health who meets the criteria in 5 CFR 2634.904 and who has not been excluded from the requirement of filing a confidential financial disclosure report under the procedures in 5 CFR 2634.905.

(2) Public filer means an employee of the National Institutes of Health who meets

the criteria in 5 CFR 2634.202 and who has not been excluded from the requirement of filing a public financial disclosure report under the procedures in 5 CFR 2634.203.

(3) Substantially affected organization has the meaning set forth in § 5501.109(b)(8).

(4) Time of acquisition means the date on which the employee actually acquired the financial interest or on which the financial interest became imputed to the employee under 18 U.S.C. 208, whether by purchase, gift, bequest, marriage, or otherwise, except that with respect to a financial interest that was acquired prior to the employee's entrance on duty as an employee of the National Institutes of Health, the "time of acquisition" shall be deemed to be the date on which the employee entered on duty. For assets held as of the effective date of this section by employees on duty at the National Institutes of Health at such time, the "time of acquisition" will be deemed to be the effective date of this section.

(c) Prohibition applicable to public and confidential filers. Except as permitted by paragraph (e) of this section, an employee of the National Institutes of Health who is required to file a public or confidential financial disclosure report pursuant to 5 CFR part 2634 and the spouse or minor child of such public or confidential filer shall not have a financial interest in a substantially affected organization.

(d) Prohibition applicable to non-filers and excluded positions. Except as permitted by paragraph (e) of this section, an employee who is not required to file a public or confidential financial disclosure report pursuant to part 2634 of this title, or who is employed in a confidential filing position excluded from the prohibited holdings

requirement pursuant to paragraph (f) of this section, or the spouse or minor child of such employee, shall not have a financial interest in a substantially affected organization unless:

(i) The total cost or value, measured at the time of acquisition, of the combined interests of the employee and the employee's spouse and minor children in the affected organization is equal to or less than the de minimis exemption limit for matters involving parties established by 5 CFR 2640.202(a) or $15,000, whichever is greater;

(ii) The holding, if it represents an equity interest, constitutes less than 1 percent of the total outstanding equity of the organization; and

(iii) The total holdings in substantially affected organizations account for less than 50 percent of the total value of the combined investment portfolios of the employee and the employee's spouse and minor children.

(e) Exceptions for certain financial interests. Notwithstanding the prohibitions in paragraphs (c) and (d) of this section:

(1) An employee or spouse or minor child of an employee may have a financial interest, such as a pension or other employee benefit, arising from employment with a substantially affected organization.

NOTE TO PARAGRAPH (e)(1): NIH employees, as opposed to spouses and minor children of employees, are generally prohibited under § 5501.109 from engaging in current employment with a substantially affected organization.

(2) An employee or spouse or minor child of an employee may have an interest in a substantially affected organization that constitutes any interest in a publicly traded or

publicly available investment fund (e.g., a mutual fund), or a widely held pension or similar fund, which, in the literature it distributes to prospective and current investors or participants, does not indicate the objective or practice of concentrating its investments in substantially affected organizations, if the employee neither exercises control nor has the ability to exercise control over the financial interests held in the fund.

(3) In cases involving exceptional circumstances, the NIH Director or the NIH Director's designee, with the approval of the designated agency ethics official or his designee, may grant a written exception to permit an employee, or the spouse or minor child of an employee, to hold a financial interest in a substantially affected organization based upon a determination that the application of the prohibitions in paragraphs (c) or (d) of this section is not necessary to ensure public confidence in the impartiality or objectivity with which HHS programs are administered or to avoid a violation of part 2635 of this title.

(4) An employee may have a financial interest in connection with the development and commercialization of invention rights obtained by the employee pursuant to Executive Order 10096, 15 U.S.C. 3710d, or implementing regulations.

NOTE TO PARAGRAPH (e): With respect to any excepted financial interest, employees are reminded of their obligations under 5 CFR part 2635, and specifically their obligation under subpart D to disqualify themselves from participating in any particular matter in which they, their spouses or minor children have a financial interest arising from publicly traded securities that exceeds the de minimis thresholds specified in the regulatory exemption at 5 CFR 2640.202 or from non-publicly traded securities that are

not covered by the regulatory exemption. Furthermore, the agency may prohibit or restrict an individual employee from acquiring or holding any financial interest or a class of financial interests based on the agency's determination that the interest creates a substantial conflict with the employee's duties, within the meaning of 5 CFR 2635.403.

(f) Exclusion of certain confidential filing positions from prohibited holdings requirement. Any individual or class of individuals described in paragraph (b)(1) of this section may be excluded from the prohibited holdings requirement of paragraph (c) of this section when the designated agency ethics official, in consultation with the NIH Director or the NIH Director's designee, determines that:

(1) The duties of the position make remote the possibility that a financial interest in a substantially affected organization would constitute a disqualifying financial interest under 18 U.S.C. 208;

(2) The application of the prohibition in paragraph (c) of this section is not necessary to ensure public confidence in the impartiality or objectivity with which HHS programs are administered or to avoid a violation of part 2635 of this title; and

(3) The individual or class of individuals does not occupy any position described below:

(i) Any position in the Office of the Director that exercises broad, agency-wide influence or authority over NIH policies, programs, or operations;

(ii) Any position in the Office of the Director or in an NIH institute or center (IC) that is specifically responsible for negotiating agreements between NIH and any substantially affected organization;

(iii) Any position involved in extramural funding decisions for biomedical or behavioral research grants, contracts, or cooperative agreements;

(iv) Any position the duties and responsibilities of which permit the employee to exert broad influence over the direction of intramural science; or

(v) Any position in which the employee is engaged in research that involves a product or service of a substantially affected organization or that is likely to have a direct and predictable effect on the financial interests of a substantially affected organization.

(g) Reporting and divestiture. For purposes of determining the divestiture period specified in 5 CFR 2635.403(d), as applied to financial interests prohibited under paragraphs (c) and (d) of this section, the "date divestiture is first directed" means the date on which the new entrant public or confidential financial disclosure report required by part 2634 of this title or any report required by § 5502.106(c) of this chapter is due.

■ 9. Add new § 5501.111 to read as follows:

§ 5501.111 Awards tendered to employees of the National Institutes of Health.

(a) Applicability. This section does not apply to special Government employees.

(b) Additional limitations on awards to employees of the National Institutes of Health. The following limitations shall apply to the acceptance by an employee of an award pursuant to 5 CFR 2635.204(d):

(1) Limitations applicable to senior employees.– (i) A senior employee shall not accept a gift with an aggregate market value of more than $200, or that is cash or an investment interest, that is an award or incident to an award given because of the employee's official position or from a prohibited source.

(ii) For purposes of this section, senior employee means the Director and the Deputy Director of the National Institutes of Health; members of the senior staff within the Office of the Director who report directly to the NIH Director; the Director, the Deputy Director, Scientific Director, and Clinical Director of each Institute and Center within NIH; Extramural Program Officials who report directly to an Institute or Center Director; and any employee of equivalent levels of responsibility who is designated as a senior employee by the designated agency ethics official or the NIH Director, in consultation with the designated agency ethics official.

(2) Limitations applicable to employees with official responsibility for matters affecting an award donor. An employee, other than a senior employee, shall not accept a gift with an aggregate market value of more than $200, or that is cash or an investment interest, that is an award or incident to an award from a person, organization, or other donor that:

(i) Is seeking official action from the employee, any subordinate of the employee, or any agency component or subcomponent under the employee's official responsibility;

(ii) Does business or seeks to do business with any agency component or subcomponent under the employee's official responsibility;

(iii) Conducts activities substantially affected by the programs, policies, or operations of any agency component or subcomponent under the employee's official responsibility; or

(iv) Is an organization a majority of whose members are described in paragraphs (b)(2)(i) through (iii) of this section.

(3) Prior approval of awards.–(i) No employee shall accept an award under 5 CFR 2635.204(d) or this section unless the receipt thereof has been approved in writing in advance in accordance with procedures specified by the designated agency ethics official, or with the concurrence of the designated agency ethics official, the NIH Director or the NIH Director's designee.

(ii) Approval shall be granted only upon a determination that acceptance of the award is not prohibited by statute or Federal regulation, including 5 CFR part 2635 and this part.

NOTE TO PARAGRAPH (b): In some circumstances cash and other things of value provided in connection with the provision of personal services, including speaking or writing, may be compensation, not a gift. Other ethics rules governing outside activities may restrict receipt of such compensation. See, for example, 5 CFR 2635.807.

(c) Exception. Notwithstanding the prohibition in paragraph (b) of this section, the NIH Director (or the Secretary, with respect to awards tendered to the NIH Director), with the approval of the designated agency ethics official, may grant a written exception to permit an employee to accept an award otherwise prohibited by this section under the following conditions:

(1) There is a determination by the NIH Director (or the Secretary, with respect to awards tendered to the NIH Director) that acceptance of the gift will further an agency interest because it confers an exceptionally high honor in the fields of medicine or scientific research. The following criteria will be considered in making such a determination:

(i) The identity of the awarding organization;

(ii) The longevity of the awards program;

(iii) The source of award funds;

(iv) The size of the monetary component of the award recognition;

(v) The identity and credentials of past award recipients;

(vi) The degree of publicity attendant to receipt of the award; and

(vii) The impact of the substantive contribution being recognized;

(2) Absent the prohibition in paragraph (b) of this section, the gift would be permitted under part 2635 of this title; and

(3) The designated agency ethics official shall have determined that the application of the prohibition in paragraph (b) of this section is not necessary to ensure public confidence in the impartiality or objectivity with which NIH programs are administered or to avoid a violation of part 2635 of this title.

(d) Disposition of improperly accepted awards—(1) Failure to obtain prior approval. If an employee accepts an award for which approval is required under paragraph (b)(3) of this section without obtaining such approval, the employee may be required, in addition to any penalty provided by law and applicable regulations, to forfeit the award by returning it to the donor.

(2) Receipt of prohibited award. If an employee accepts an award prohibited by paragraph (b) of this section, the employee shall be required, in addition to any penalty provided by law and applicable regulations, to:

(i) Reject the award and instruct the donor to strike the honoree's name from any list of award recipients;

(ii) Remove the recognition from the employee's résumé or curriculum vitae;

(iii) Return any tangible indicia of the recognition to the donor; and

(iv) Forfeit the award by returning it to the donor.

■ 10. Add new § 5501.112 to read as follows:

§ 5501.112 One-year disqualification of employees of the National Institutes of Health from certain matters involving an award donor.

An employee, other than a special Government employee, of the National Institutes of Health who has, within the last year, accepted an award permitted under 5 CFR 2635.204(d) or § 5501.111 shall not participate in any particular matter involving specific parties in which the donor is or represents a party unless authorized to do so under 5 CFR 2635.502(d).

PART 5502 – SUPPLEMENTAL FINANCIAL DISCLOSURE REQUIREMENTS FOR EMPLOYEES OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

■ 11. Add new part 5502 to read as follows:

PART 5502 – SUPPLEMENTAL FINANCIAL DISCLOSURE REQUIREMENTS FOR EMPLOYEES OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

Sec.

AUTHORITY: 5 U.S.C. 301, 7301; 5 U.S.C. App. (Ethics in Government Act of 1978); E.O. 12674, 54 FR 15159, 3 CFR, 1989 Comp., p. 215, as modified by E.O. 12731, 55 FR 42547, 3 CFR, 1990 Comp., p. 306; 5 CFR 2634.103.

§ 5502.101 General.

The regulations in this part apply to employees of the Department of Health and Human Services and supplement the Executive Branch Financial Disclosure Regulations in 5 CFR part 2634. Any regulation in this part made applicable only to the employees of an HHS component designated as a separate agency under § 5501.102(a) of this chapter shall apply to the employees of that component as defined in § 5501.102(b)(1) of this chapter.

§ 5502.102 Annual supplemental report of outside employment or activities.

Any employee, other than a special Government employee, for whom an outside employment or activity has been approved, or who has participated in any outside employment or activity for which prior approval is required, under part 5501 of this chapter shall file on or before February 28 of each year a report concerning all such activities that were approved or undertaken in the previous calendar year. The annual report shall be filed with the employee's supervisor who shall review the form, in consultation with an agency ethics official, and determine whether the employee has complied with applicable laws and regulations and whether approval of any ongoing outside activity should be cancelled because the activity does not meet the standard in § 5501.106(d)(4) of this chapter.

§ 5502.103 Content of annual supplemental reports.

The annual supplemental report of outside employment or activities required by § 5502.102 shall include the following information:

(a) The employee's name, contact information, organizational location, occupational title, grade, step, salary, appointment type, and financial disclosure filing status;

(b) A list of all outside activities for which prior approval is required under part 5501 of this chapter that were approved pursuant to 5 CFR 5501.106(d) or undertaken within the reporting period. The report must identify the person or organization for whom or with which the employee was to perform the activity and the approval date;

(c) A statement as to whether the anticipated work described in a previously approved outside activity was actually performed for the person or organization named in the request for approval;

(d) For each outside activity actually performed, the beginning date of the relationship with the outside entity, the date(s) personal services were provided, the total number of hours spent and leave used on the activity within the reporting period, and the ending date;

(e) For each outside activity that remains ongoing at the time of filing the report, a statement as to how long the activity is anticipated to continue, the date on which prior approval expires, and whether a request for renewal of approval is anticipated;

(f) For each outside activity actually performed, the type and amount of any income and/or reimbursements actually received during the reporting period and the date paid;

(g) For each outside activity actually performed, the type and amount of any income and/or reimbursements earned during or attributable to the reporting period that were not in fact received during the reporting period and remain due;

(h) A statement as to whether any change has occurred or is anticipated with respect to information supplied in the original outside activity approval request;

(i) A description of any change in the nature, scope, or subject matter of any approved activity; and

(j) A description of any change in jobs or in the duties and responsibilities of the employee's position that occurred after the outside activity was approved.

§ 5502.104 Confidentiality of reports.

Each report filed under this part is confidential and shall not be disclosed to the public, except as provided under § 2634.604(b) of this title.

§ 5502.105 Agency procedures.

The designated agency ethics official or, with the concurrence of the designated agency ethics official, each of the separate agency components of HHS listed in § 5501.102(a) of this chapter may prescribe procedures for the submission and review of each report filed under this part. These procedures may provide for filing extensions, for good cause shown, totaling not more than 90 days.

§ 5502.106 Supplemental disclosure of prohibited financial interests applicable to employees of the Food and Drug Administration and the National Institutes of Health.

(a) Applicability. This section does not apply to special Government employees.

(b) Definitions. For purposes of this section:

(1) Confidential filer means an employee who meets the criteria in 5 CFR 2634.904 and who has not been excluded from the requirement of filing a confidential financial disclosure report under the procedures in 5 CFR 2634.905.

(2) Prohibited financial interest means a financial interest prohibited by § 5501.104(a) or §§ 5501.110(c) and (d) of this chapter for FDA or NIH employees respectively, including those financial interests that are excepted under §§ 5501.104(b) or 5501.110(e) or permitted under paragraphs (d)(i) through (d)(iii) of § 5501.110 of this chapter.

(3) Public filer means an employee who meets the criteria in 5 CFR 2634.202 and who has not been excluded from the requirement of filing a public financial disclosure report under the procedures in 5 CFR 2634.203.

(4) Remainder of HHS has the meaning set forth in § 5501.102(b)(2) of this chapter.

(5) Separate agency component has the meaning set forth in § 5501.102(a) of this chapter.

(c) Report of prohibited financial interests.–(1) New entrant employees. A new entrant employee, other than a public filer or a confidential filer, shall report in writing within 30 days after entering on duty with the FDA or the NIH any prohibited financial interest held upon commencement of employment with the agency.

(2) Reassigned employees. An employee of a separate agency component, other than the FDA or the NIH, or of the remainder of HHS who is reassigned to a position at the FDA or the NIH shall report in writing within 30 days of entering on duty with the FDA or the NIH any prohibited financial interest held on the effective date of the reassignment to the agency.

(3) Incumbent employees. An incumbent employee of the FDA or the NIH who acquires any prohibited financial interest shall report such interest in writing within 30 days after acquiring the financial interest. An employee on duty at the NIH who is subject to § 5501.110(c) of this chapter as of [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER], the effective date of this rule, shall report in writing within 60 days after the effective date any prohibited financial interest held on the effective date.